MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISION MEETING

Tuesday, September 18, 2007

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Hagenow called the meeting to order at 9:07 a.m.

A. Members Present:

Norma Hagenow, Chairperson
Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO
Bradley N. Cory, (Left @ 2:57 p.m.)
Dorothy E. Deremo, (Left @ 12:08 p.m.)
Marc Keshishian, MD
Adam Miller, (Via teleconference from 9:15 a.m. to 12:13 p.m.)
Michael A. Sandler, MD
Michael W. Young, DO

B. Members Absent:

Kathie VanderPloeg-Hoekstra

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Umbrin Ateequi
Mike Dankert
William Hart
Larry Horvath
John Hubinger
Joette Laseur
Irma Lopez
Nick Lyon
Andrea Moore
Rose Moye
Stan Nash
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Chairperson Hagenow recommended moving item IX, Psychiatric Beds and Services – Workgroup Report, to item VI.

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to accept the agenda as modified. Motion Carried.

III. Declaration of Conflicts of Interest

No conflicts were stated at this time.

IV. Review of Minutes – June 13, 2007

Motion by Commissioner Ajluni, seconded by Commissioner Sandler, to approve the minutes as presented. Motion Carried.

V. Public Comment for Action Items (i.e., VI, VII, VIII, IX, X, XI, & XII)

Psychiatric Beds and Services

Amy Barkholz, MHA
Mark Mailloux, University of Michigan Health System (Attachment A)
Liz Palazzolo, Henry Ford
Bob Meeker, Spectrum Health

Magnetic Resonance Imaging (MRI) Services

Jim Foresman, Miller, Canfield

Air Ambulance (AA) Services

Judy Kettenstock, Trinity Health Midwest Medflight (Attachment B)

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units

Anne Mitchell, Great Lakes Lithotripsy

Open Heart Surgery (OHS) Services

Patrick O'Donovan, William Beaumont
Sandy Reoma, Blue Care Blue Shield of Michigan
Aaron Kugelmass, Henry Ford Hospital
Marsha Manning, General Motors
Cassandra Saunders, Chrysler
Bob Meeker, Spectrum Health (Attachment C)

Neonatal Intensive Care (NICU) Services/Beds

Patrick O'Donovan, William Beaumont

Cardiac Catheterization (CC) Services

Patrick O'Donovan, William Beaumont
Robert Klimek, MD, Blue Care Network

Miscellaneous Standards

Larry Horwitz, Economic Alliance for Michigan

VI. Psychiatric Beds and Services – Workgroup Report

A. Review of Proposed Language

Ms. Deremo provided the Commission with a brief summary of the Workgroup's recommendations (Attachment D). Ms. Moore reviewed the technical changes that were made to the proposed language (Attachment E).

B. Commission Proposed Action

Motion by Commissioner Sandler, seconded by Commissioner Deremo, to accept the proposed language of the Workgroup and move to Public Hearing and Joint Legislative Committee (JLC). Motion Carried.

VII. CC Services Standard Advisory Committee (SAC) – Final Report

A. Review of Proposed Language

Chairperson Joseph of the CCSAC provided a brief report (Attachment F) of the recommendations by the SAC. Ms. Amarnath reviewed the proposed language (Attachment G) made by the CCSAC. Discussion followed.

B. Commission Proposed Action

Motion by Vice-Chairperson Goldman, seconded by Commissioner Keshishian, to approve the CCSAC recommendations and move to Public Hearing and JLC. Motion Carried.

VIII. OHSSAC – Final Report

A. MDCH Report & Review of Proposed Language

Vice-Chairperson Raica of the OHSSAC read the memorandum (Attachment H) by Chairperson Delaney of the OHSSAC. Ms. Ateequi reviewed the proposed language (Attachment I) by the SAC.

B. Commission Discussion

Commissioner Sandler questioned whether or not the SAC took into account geography when making their recommendations. OHSSAC member Dr. Kugelmass addressed Dr. Sandler's question. He stated that the SAC did consult maps of Michigan to look at location and felt the SAC did address the issue.

Commissioner Keshishian questioned if the SAC addressed access. Dr. Kugelmass stated the SAC did look at the access issue. He stated the SAC does not feel there is an access issue via the geography of the state, and at the same time, the SAC did not reach a consensus as to whether or not there is a need for future programs moving forward.

Commissioner Keshishian questioned if the SAC discussed the fact that there are three potential additional programs in southeast Michigan and what we are doing is potentially allowing people to open up programs, and the employers of this state will have to pay for all of that and then just to close them down after three years. Vice-Chairperson Raica

stated that she felt that is one of the reasons why the SAC made the recommendation about not being able to recommit MIDB data to another program after seven years.

Public Comment

Sandy Reoma, Blue Cross Blue Shield of Michigan

Ms. Ateequi reviewed the technical changes to the language.

C. Commission Proposed Action

Motion by Vice-Chairperson Goldman, seconded by Commissioner Cory, to accept the OHSSAC report, adopt the recommendations contained in the report for purposes of moving it forward to Public Hearing and JLC, request that both the comments at the Public Hearing and by the Department look at the geographic implications of the current language, look at implications for new programs, look at implications of Section 6(1)(b) and Section 6(2)(b) in terms of the potential for double counting of data, and look at the methodology which include but are not limited to weighting, volume and use of primary versus secondary data. Motion Carried.

Lunch break from 12:13 p.m. 1:04 p.m.

IX. AA Services – Public Hearing Comments

A. Commission Discussion

Ms. Moore provided a brief summary (Attachment J) of the comments received at the Public Hearing. Mr. Styka provided the Attorney General's opinion regarding AA Services. He stated the Commission could request a formal opinion from the Attorney General's office and table action on this item until the next meeting. He also stated the Commission could proceed only with Standards that would be consistent with the declaratory ruling which attempts to say that anything other than need can be developed into Standards.

B. Commission Final Action

Motion by Commissioner Sandler, seconded by Commission Cory, to table final action on AA Services until the December meeting and request an opinion from the Attorney General's office. Motion Carried.

Chairperson Hagenow will prepare and send the request to the Attorney General's office.

X. NICU Services/Beds – Public Hearing Comments

A. Commission Discussion

Ms. Moore stated the Department did not receive any public comment regarding the NICU Services/Beds.

B. Commission Final Action

Motion by Commissioner Keshishian, seconded by Commissioner Ajluni, to approve the language and move forward to the JLC and Governor for the 45-day review period. Motion Carried.

XI. MRI Services – Public Hearing Comments

A. Commission Discussion

Ms. Rogers stated the Department did not receive any written or oral testimony regarding the MRI Services language.

B. Commission Final Action

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to approve the language and move forward to the JLC and Governor for the r4-day review period. Motion Carried.

XII. UESWL Services/Units

A. MDCH Report & Review of Proposed Language

Ms. Rogers provided a brief overview of the technical changes made to the language (Attachment K).

B. Commission Proposed Action

Motion by Vice-Chairperson Goldman, seconded by Commissioner Sandler, to accept the language and move forward to Public Hearing and JLC. Motion Carried.

XIII. Computed Tomography (CT) Scanner Services SAC – Status Report

Ms. Ateequi gave a brief overview of Chairperson Shumaker's report (Attachment L).

Commissioner Sandler stated that the issue of Specialty-Use Scanners has not yet been discussed in the SAC and is an issue that they need to address.

XIV. Nursing Home and Hospital Long-term Care (NH-HLTC) Unit Beds SAC – Status Report

Ms. Moore provided a brief overview on the progress of the SAC.

XV. Standing New Medical Technology Advisory Committee (NEWTAC) – Report

Commissioner Keshishian provided a brief report (Attachment M) on the progress of the Committee. He reported the Committee has met twice since the last Commission meeting. He stated the Committee recommends not regulating neurointerventional radiology at this time.

It was requested that neurointerventional radiology be added to the Commission's December meeting agenda as an action item.

XVI. Legislative Report

Mr. Lyon provided a brief introduction of himself. He reported that there is no pending legislation at this time.

Chairperson Hagenow reported that Vice-Chairperson Goldman and she have been meeting with some of the Legislators. She recommended that all the Commissioners speak with their representing Legislator and inform them of the work that the Commission has been doing.

XVII. Compliance Report

Mr. Lyon provided a brief overview of the report (Attachment N).

Mr. Horvath provided a brief clarification on the compliance issue.

XVIII. Administrative Update

Mr. Hart stated that our Department continues to utilize other staff to assist with CON activity.

XIX. CON Program Update

Ms. Rogers stated there is no oral report, but a written report has been provided (Attachment O).

XX. Legal Activity Report

Mr. Styka gave a brief overview of the report (Attachment P) regarding the CON Legal Activities.

XXI. Future Meeting Dates

December 11, 2007
March 11, 2008
June 11, 2008
September 16, 2008
December 9, 2008

XXII. Public Comment

Bob Meeker, Spectrum Health
Larry Horwitz, Economic Alliance for Michigan

XXIII. Work Plan

Ms. Rogers provided a brief overview of the work plan (Attachment Q).

Motion by Commissioner Goldman, seconded by Commissioner Ajluni, to approve the work plan. Motion Carried.

XXIV. Adjournment

Motion by Commissioner Keshishian, seconded by Vice-Chairperson Goldman, to adjourn the meeting at 2:11 p.m. Motion Carried.

University of Michigan
Health System

Mark Mailloux
Senior Health System Planner

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September 18, 2007

Certificate of Need Commissioners
c/o Brenda Rogers
Capitol View Building
201 Townsend Ave.; 7th Floor
Lansing, MI 48913

Ladies & Gentlemen of the Commission:

I am Mark Mailloux, Senior Health System Planner at the University of Michigan Health System. The University of Michigan Health System wishes to take this opportunity to comment on the proposed revisions to the Certificate of Need Standards for Psychiatric Beds.

First of all, we would like to commend Commissioner Deremo and all of the participants who gave of their time and expertise to bring this initiative forward before you today. We believe that, in general, these proposed revisions to the Psychiatric Hospital Bed Standards represent a positive step forward.

Our main concern, however, is one of degree rather than substance. We feel that the 1.7 multiplication factor employed for the Child & Adolescent service while absolutely supportable in concept is, nonetheless, inadequate. We believe that the occupancy swings in this service are so extreme that a factor of at least 2.0 or even greater is required to offset the peaks and valleys these units experience in census. An examination by MHA of the four hospitals with Child & Adolescent Psych beds showed that the maximum census exceeded the average by 1.6, 2.0, 2.2, & 3.0 times. Clearly the 1.7 multiplier is inadequate to accommodate such swings in occupancy. We would ask that the Commission consider adjusting this factor for Child & Adolescent beds.

Thank you for this opportunity to address the standard setting process and to these standards in particular. With the exception of this solitary reservation, The University of Michigan Health System wholeheartedly supports these proposed standards.

Thank you.

From: <DoNotReply@michigan.gov>
To: <moorean@michigan.gov>
Date: Thu, Sep 13, 2007 11:05 AM
Subject: Written Testimony for September 18, 2007 Commission Meeting (ContentID - 147062)

1.+Name: Judith Kettenstock
2.+Organization: Saint Joseph Mercy Health System/ Midwest Medflight
3.+Phone: 734-712-3104
4.+Email: kettensj@trinity-health.org
5.+Standard: Air Ambulance CON
6.+Testimony: Midwest Medflight would like to comment on the proposed revisions to the CON Review Standards for Air Ambulance Services, which was approved for public comment by the CON Commission on June 13, 2007. In general, Midwest Medflight is supportive of the proposed changes.

We are writing to support the suggested changes that were submitted by Spectrum Health for Section X. An applicant proposing to change the base of operations of an existing air ambulance shall:

Sec. X. An applicant proposing to change the base of operations of an existing air ambulance shall:

(1) demonstrate that in the most recent 12-month period for which verifiable data are available to the Department, the air ambulance service met one (1) of the following:.

(a) 275 patient transports for an air ambulance service with one (1) air ambulance;

(b) 600 patient transports and organ transports for an air ambulance service with two (2) air ambulances, of which 550 must be patient transport;

(c) 1,200 patient transports and organ transports for an air ambulance service with three (3) air ambulances, of which 825 must be patient transport;

(d) 1,800 patient transports and organ transports for an air ambulance service with four (4) air ambulances, of which 1,100 must be patient transport.

(2) maintain the same base hospital(s) of the existing air ambulance service.

(3) identify the proposed base of operations, and comply with all of the following:

(a) provide a letter of support from the medical control authority for the proposed base of operations indicating that the applicantÆs protocols comply with the requirements of the medical control authority;

(b) demonstrate that all existing air ambulance services with a base of operations within a 75-mile radius of the proposed new base of operations of the air ambulance service have been notified of the applicant's intent to change the base of operations, by means of a certified mail return receipt dated before the deemed complete date of the application; and

(c) demonstrate that the proposed new base of operations is within the same health service area as the existing base of operations.

This section as it currently stands in the proposed changes would prohibit Midwest Medflight from operation out of its current hangar at Willow Run Airport, which is located in Wayne County a different medical control authority, or operating out of another hangar if a change was required. The proposed wording submitted by Spectrum Health would allow us to continue to operate and make changes if financially we were required to do so.

Thank you for the opportunity to comment on the proposed revisions to the CON Review Standards for Air Ambulance Services.

Sincerely,

Judy Kettenstock RN, MSN
Program Director
Midwest Medflight

Spectrum Health
BUTTERWORTH CAMPUS

100 Michigan Street NE Grand Rapids MI 49503-2560
616 391 1774 fax 391 2745

September 18, 2007

Norma Hagenow, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Ms. Hagenow,

This letter is formal testimony by Spectrum Health about several issues on the agenda of the CON Commission meeting on September 18, 2007; namely proposed CON Review Standards for Cardiac Catheterization, Open-Heart Surgery, and Air Ambulance Services. Spectrum Health appreciates the opportunity to comment on these Standards.

As a general statement, Spectrum Health supports the CON process, including the procedures established in law for reviewing and updating the CON Review Standards. Spectrum Health commends the work of the Commission and its advisory committees and work groups. While Spectrum Health does not always agree with the Commission's decisions, we support the process and are committed to abide by those decisions. We believe that the Commission faithfully carries out the responsibilities assigned by the legislature. The process of reviewing and updating CON Review Standards works well for the citizens of Michigan.

Cardiac Catheterization Services

The Standards Advisory Committee (SAC) for Cardiac Cath has completed an excellent job of revising the CON Review Standards. They updated the procedure weights and the requirements for advanced pediatric cardiac services, while maintaining the requirement that elective angioplasty should be performed only in hospitals which have on-site open-heart surgery back-up. This recommendation conforms to the guidelines of the American College of Cardiology (ACC), which represents the best judgment of the profession.

Spectrum Health supports the recommendations of the Cardiac Cath SAC.

Open-Heart Surgery

Spectrum Health endorses the conclusion that there is no need for additional open-heart surgery programs in Michigan and that the citizens of the state are

applicable in rural areas. We believe that, when expanding an air ambulance service, the base of operations of the additional aircraft should be allowed to be located anywhere in the same health service area (HSA) as the existing base of operations, rather than being confined to a single medical control authority. The mission of an air ambulance service is to reduce the time required to bring advanced medical services to patients in life-threatening circumstances. Having the ability to operate multiple helicopters from bases of operations in different medical control authorities within the HSA will improve the timeliness of these services and will increase the ability of air ambulance operators to accomplish their mission.

3) Under the existing Standards, "base of operations" is defined as a hospital. The proposed revisions define the base of operations as the place where the aircraft and crew are stationed. Since a CON is specific to an identified location (in the case of air ambulance services, the base of operations), a new section should be added to the Standards to allow relocation of the base of operations. Without such a change, an air ambulance operator would not be permitted to change the hanger location of the aircraft, which may need to occur for any number of reasons. We suggest that a new relocation section be added to the Standards, with requirements paralleling the replacement requirements (Section 5), and permitting relocation of the base of operations within the HSA, as discussed above.

Our public testimony included suggested language corresponding to these comments.

We appreciate the opportunity to comment on these pending CON policy decisions.

Sincerely,

Robert A. Meeker
Strategic Program Manager

Psychiatric Beds and Services Workgroup 2006 - 2007
Final Report to the Certificate of Need Commission

September 18, 2007

The Psychiatric Beds and Services Workgroup was established at the March 21, 2006 Certificate of Need (CON) Commission Meeting. The Commission assigned the Workgroup to follow up on the public comments received at the Public Hearing on January 31, 2006. An overview of the public comments is below:

- Received three (3) recommendations to review the Bed Need Methodology for possible modifications.
- Received four (4) recommendations to review the Planning Areas for possible modifications.
- Received three (3) recommendations for the addition of individual facility high occupancy language.
- Received four (4) recommendations for review of the Replacement Zone for possible modifications.
- Received one (1) recommendation for the addition of Relocation definition and language.
- Received one (1) recommendation for removal of Section 6(2)(f).
- Received one (1) recommendation for review of the Michigan Mental Health Commission Final Report for potential inclusion.

Additionally, the Department requested the review of the occupancy rates for possible adjustment and several technical changes. The department request and public comments comprised the list of discussion items. The Workgroup evaluated each discussion item and offered several different modification options. Concepts were then applied to actual facility data to ensure the proposed modifications did not have any unintended or adverse effects. The following is an overview of the discussion items and the Workgroup recommendations:

1. Review Bed Need Methodology.

   Maintain the Bed Need Methodology to determine overall planning area need with the addition of an adjustment for low occupancy facilities. The methodology will be calculated every two years.

   The low occupancy adjustment will involve facilities with 60% or lower average occupancy for the previous two years. For each facility, the average daily census will be multiplied by 1.5 for adult beds and 1.7 for child/adolescent beds, giving an adjusted number of beds. The net decrease from the current beds, per HSA, will be the low occupancy adjustment.

The affect on the Adult Bed Need utilizing October 2004 – September 2006 data is as follows:

HSA	Current Bed Need	Adjustment For Low Occupancy Facilities	Adjusted Bed Need	Current Licensed Beds	Bed Need or (Excess)
1	1019	35	1054	1223	(169)
2	163	26	189	145	44
3	164	23	187	153	34
4	228	16	244	248	(4)
5	129	51	156	144	36
6	151	5	162	106	50
7	56	3	59	43	16
8	75	0	75	37	38
Totals	1985	159	2144	2099	45

2. Review planning areas for both Adult and Child/Adolescent.

   Modify the adult planning areas from the Community Mental Heath boundaries to HSA boundaries. This correlates to the more regional nature of psychiatric services. Additionally, both adult and child/adolescent will have the same planning areas.

3. Review occupancy rates.

   Modify the minimum annual average occupancy rate within the project delivery requirements, for adult beds from 85% to 60%, and for child adolescent beds from 75% to 40%. Additionally, if a facility falls below these levels, the facility must reduce the number of beds, but not less than 10 beds, to achieve the above occupancy rates.

   The child/adolescent occupancy rates are set lower due to the extreme fluctuation of patient utilization. During peak times, facilities are full to capacity. However, at other times, the facilities have very low daily census. Thus, the average annual occupancy is much lower for these facilities.

   Pine Rest Christian Mental Health, Forest View Psychiatric Hospital, Borgess Medical Center, Healthsource Saginaw, and University of Michigan have provided an overview of the average daily census on a monthly basis over a two year period. The graphs and data are attached.

The following chart gives the average annual occupancy rates for all child/adolescent facilities from October 2005 – September 2006:

HSA	Facility No.	Facility Name	County	Current Beds	10/05 - 09/06	
					PT Days	Occupancy Rate
1	50-2530	Harbor Oaks Hospital	Macomb	24	3,996	45.62%
1	63-2510	Henry Ford Kingswood Hospital	Oakland	30	4,761	43.48%
1	63-2530	Havenwyck Hospital	Oakland	55	11,622	57.89%
1	81-0060	University of Michigan Hospital	Washtenaw	32	3,088	26.44%
1	83-2633	Circle of Life Center	Wayne	30	3,482	31.80%
3	39-0010	Borgess Medical Center	Kalamazoo	12	1,084	24.75%
4	41-2510	Forest View Psychiatric Hospital	Kent	22	4,997	62.23%
4	41-2530	Pine Rest Christian Mental Hlth	Kent	48	8,638	49.30%
5	25-0040	Hurley Medical Center	Genesee	18	1,489	22.66%
6	73-0060	Healthsource Saginaw	Saginaw	14	2,279	44.60%
8	52-0050	Marquette General Hospital	Marquette	6	1,332	60.82%

4. Discuss establishing an individual facility high occupancy exception.

Addition of a high occupancy provision, that allows expansion outside of the bed need for a facility with 19 beds or less with an average occupancy rate of 75% for previous two years; or for a facility with 20 beds or more with an average occupancy rate of 80% for previous two years. A qualifying facility can request the additional number of beds utilizing the formula: the average daily census will be multiplied by 1.5 for adult beds and 1.7 for child/adolescent, giving an adjusted number of beds.

The following is an overview of the number of facilities and number of beds possible utilizing occupancy rates for October 2004 – September 2006 data:

HSA	Facilities of 19 beds for less with 75% Average Occupancy		Facilities of 20 beds or more with 80% Average Occupancy	
	No. of Facilities	Number of Beds	No. of Facilities	Number of Beds
1	0	0	8	84
2	0	0	0	0
3	0	0	1	16
4	2	9	4	64
5	1	4	0	0
6	0	0	0	0
7	1	4	0	0
8	0	0	0	0
Totals	4	17	13	164

Thus, 17 facilities would be eligible to apply for high occupancy and request 181 beds.

5. Review replacement zone.

   Modify the replacement zone by increase the mileage from 2 to 15 miles within the planning area.

6. Discuss relocation of an existing licensed bed to another facility.

   The Workgroup concluded that this concept was not necessary within these Standards. No action or modifications were made.

7. Review the 1 bed for 20 bed exception within the requirements for initiation and increase of beds.

   Modify the exception from 20 beds to 10 beds, if the bed need is 9 beds or less in the planning area.

8. Review the minimum number of beds per psychiatric unit.

   Modify the minimum number of beds in a psychiatric unit from 20 beds to 10 beds. This will allow Critical Access Hospitals to initiate a unit.

9. Technical changes and updates of the Department.

   The Department requested technical changes and updates were added as requested. Old terminology and language was removed from the Standards.

10. Additional changes. Increase in beds was modified to allow additional beds to a facility with 70% average occupancy for previous two years.

The Workgroup has concluded their work on the discussion items and has drafted changes to Standards for possible proposed action.

The overall informal Workgroup meeting model was evaluated by participants and comments offered were very positive. The Workgroup noted that the inclusion of all interested parties was very helpful and that round-table questioning allowed all participants the time to speak. In addition, having meeting materials provided prior to the meeting helped the Workgroup stay focused and on task.

Respectfully submitted,

Dorothy E. Deremo, CON Commission Liaison
Psychiatric Beds and Services Workgroup

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws).

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve psychiatric beds and services.

(2) A psychiatric hospital or unit is a covered health facility for purposes of Part 222 of the Code.

(3) An increase in licensed psychiatric beds or the physical relocation from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.

~~(4) The initiation or expansion of a specialized psychiatric program for children/adolescents is a covered clinical service for purposes of Part 222 of the Code.~~

(~~5~~4) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, and ~~9~~10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(~~6~~5) The Department shall use sections ~~11~~ 12 and ~~12~~13, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(6) THE DEPARTMENT SHALL USE SECTION 11 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

~~(a) "Adult" means any individual aged 18 years or older.~~

(~~b~~A) "Acquisition of a psychiatric hospital or unit" means the issuance of a new license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed psychiatric hospital or unit and which does not involve a change in the number of licensed psychiatric beds ~~or beds designated for a child/adolescent specialized psychiatric program~~ at that health facility.

(B) "ADULT" MEANS ANY INDIVIDUAL AGED 18 YEARS OR OLDER.

(c) "Base year" means 1992 or the most recent year for which verifiable data are collected by the Department and are available separately for the population age cohorts of 0 to 17 and 18 and older.

~~(d) "Child/adolescent" means any individual less than 18 years of age.~~

(~~e~~D) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(E) "CHILD/ADOLESCENT" MEANS ANY INDIVIDUAL LESS THAN 18 YEARS OF AGE.

(f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(g) "Community mental health board" or "board" or "CMH" means the board of a county(s) community mental health board ~~as defined in Section 200(b) of Act 258 of the Public Acts of 1974, as amended, being Section 330.1200(b) of the Michigan Compiled Laws~~ AS REFERENCED IN THE PROVISIONS OF MCL 330.1200 TO 330.1246.

(h) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

~~(i) "Converted beds" means existing licensed psychiatric beds reallocated from one program category to child/adolescent.~~

(~~i~~I) "Department" means the Michigan Department of Community Health (MDCH).

(~~k~~J) "Department inventory of beds" means the current list maintained by the Department which includes:

(i) licensed adult and child/adolescent psychiatric beds; and

(ii) adult and child/adolescent psychiatric beds approved by a valid CON, ~~issued under either former Part 221 or Part 222 of the Code~~ which are not yet licensed.

A separate inventory will be maintained for child/adolescent beds and adult beds.

(~~l~~K) "Existing adult inpatient psychiatric beds" or "existing adult beds" means:

(i) all adult beds in psychiatric hospitals or units licensed by the Department pursuant to the Mental Health Code;

(ii) all adult beds approved by a valid CON, ~~issued under either former Part 221 or Part 222 of the Code~~ which are not yet licensed;

(iii) proposed adult beds under appeal from a final Department decision ~~made under former Part 221 or Part 222~~, or pending a hearing from a proposed decision ~~issued under Part 222 of the Code~~; and

(iv) proposed adult beds that are part of a completed application ~~under Part 222 of the Code~~ (other than the application or applications in the comparative group under review) which are pending final Department decision.

(~~m~~L) "Existing child/adolescent inpatient psychiatric beds" or "existing child/adolescent beds" means:

(i) all child/adolescent beds in psychiatric hospitals or units licensed by the Department pursuant to the Mental Health Code;

(ii) all child/adolescent beds approved by a valid CON, ~~issued under either former Part 221 or Part 222 of the Code~~ which are not yet licensed;

(iii) proposed child/adolescent beds under appeal from a final Department decision ~~made under former Part 221 or Part 222~~, or pending a hearing from a proposed decision ~~issued under Part 222 of the Code~~; and

(iv) proposed child/adolescent beds that are part of a completed application ~~under Part 222 of the Code~~ (other than the application or applications in the comparative group under review) which are pending final Department decision.

~~(n) "Expansion of a child/adolescent specialized psychiatric program" means an increase in the number of beds designated for children/adolescents whether through an increase in the total number of licensed psychiatric beds or the conversion of existing licensed beds.~~

(~~o~~M) "Initiation of SERVICE ~~a specialized psychiatric program for children/adolescents~~ " means the establishment of an inpatient psychiatric unit with a specified number of beds ~~designated for children/adolescents~~ at a site ~~at which specialized psychiatric program services are~~ not currently ~~provided~~ PROVIDING PSYCHIATRIC SERVICES.

(~~p~~N) "Involuntary commitment status" means a hospital admission effected pursuant to the provisions of MCL~~A~~ 330.1423 to ~~MCLA 330.1444~~ 330.1429.

(~~q~~O) "Licensed site" means either:

(i) in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(~~r~~P) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(~~s~~Q) "Mental Health Code" means Act 258 of the Public Acts of 1974, as amended, being Sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(~~t~~R) "Mental health professional" means aN ~~person~~ INDIVIDUAL who is trained and experienced in the area~~s~~ of mental illness or ~~mental retardation~~ DEVELOPMENTAL DISABILITIES and who is any 1 of the following:

(i) a physician who is licensed to practice ~~allopathic~~ medicine or osteopathic medicine AND SURGERY in Michigan and who has had substantial experience with mentally ill, mentally retarded, or developmentally disabled clients for 1 year immediately preceding his or her involvement with a client under administrative rules promulgated pursuant to the Mental Health Code;

(ii) a psychologist WHO IS LICENSED IN MICHIGAN PURSUANT TO THE PROVISIONS OF MCL 333.16101 TO 333.18838;

(iii) a ~~certified~~ LICENSED MASTER'S social worker LICENSED IN MICHIGAN PURSUANT TO THE PROVISIONS OF MCL 333.16101 TO 333.18838;

(iv) a registered nurse WHO IS LICENSED IN MICHIGAN PURSUANT TO THE PROVISIONS OF MCL 333.16101 TO 333.18838;

(V) A LICENSED PROFESSIONAL COUNSELOR LICENSED IN MICHIGAN PURSUANT TO THE PROVISIONS OF MCL 333.16101 TO 333.18838;

(VI) A MARRIAGE AND FAMILY THERAPIST LICENSED IN MICHIGAN PURSUANT TO THE PROVISIONS OF MCL 333.16101 TO 333.18838;

(~~v~~VII) a professional person, other than those defined in the administrative rules promulgated pursuant to the Mental Health Code, who is designated by the Director of the Department or a director of a facility operated by the Department in written policies and procedures. This mental health professional shall have a degree in his or her profession and shall be recognized by his or her respective professional association as being trained and experienced in the field of mental health. The term does not include non-clinical staff, such as clerical, fiscal or administrative personnel.

(~~u~~S) "Mental health service" means ~~a service that is directed to the areas of mental illness, mental retardation, developmental disability, other organic brain or other neurological impairment or disease, alcoholism, or substance abuse pursuant to Section 208 of the Mental Health Code~~ THE PROVISION OF MENTAL HEALTH CARE IN A PROTECTIVE ENVIRONMENT WITH MENTAL ILLNESS OR MENTAL RETARDATION, INCLUDING, BUT NOT LIMITED TO, CHEMOTHERAPY AND INDIVIDUAL AND GROUP THERAPIES PURSUANT TO MCL 330.2001.

(~~v~~T) "Non-renewal or revocation of license" means the Department did not renew or revoked the psychiatric hospital's or unit's license based on the hospital's or unit's failure to comply with state licensing standards.

(~~w~~U) "Non-renewal or termination of certification" means the psychiatric hospital's or unit's Medicare and/or Medicaid certification was terminated or not renewed based on the hospital's or unit's failure to comply with Medicare and/or Medicaid participation requirements.

(~~x~~V) "Offer" means to provide inpatient psychiatric services to patients.

~~(y) "Partial hospitalization psychiatric program" or "partial hospitalization" or "program" means a non-residential mental health treatment program which:~~

~~(i) is operated and clients are regularly scheduled to be treated for a minimum of six consecutive hours during any 24 hour period for a minimum of 5 days per week;~~

~~(ii) includes psychiatric, psychological, social, occupational and therapeutic recreational elements all of which are under psychiatric supervision; and~~

~~(iii) provides services to clients who are diagnosed mentally or emotionally ill and who are at risk of psychiatric inpatient hospitalization, or who might otherwise remain hospitalized on an inpatient basis in the absence of such a program, due to: subacute homicidal or suicidal behavior; acute psychosis; acute phases of major affective disorders; or the need for supervised diagnostic tests, observations, or supervised administration of medication when extended observation is necessary.~~

(~~z~~W) "Physician" means an individual licensed IN MICHIGAN ~~under Article 15 of the Code~~ to engage in the practice of medicine or osteopathic medicine and surgery PURSUANT TO MCL 333.16101 TO 333.18838.

(~~aa~~X) "Planning area" means ~~either:~~

~~(i) for child/adolescent beds and services,~~ the geographic boundaries of the groups of counties shown in Section ~~14(1)~~15; ~~or~~

~~(ii) for adult beds and services, the county or groups of counties served by each CMH as shown in Section 14(2)~~.

(~~bb~~Y) "Planning year" means 1990 or a year in the future, at least 3 years but no more than 7 years, established by the CON Commission for which inpatient psychiatric bed needs are developed. The

planning year shall be a year for which official population projections from the Department of Management and Budget are available.

(~~cc~~Z) "Psychiatric hospital" means ~~a health facility licensed under the Mental Health Code as defined in R330.1201~~ AN INPATIENT PROGRAM OPERATED BY THE DEPARTMENT FOR THE TREATMENT OF INDIVIDUALS WITH SERIOUS MENTAL ILLNESS OR SERIOUS EMOTIONAL DISTURBANCE OR A PSYCHIATRIC HOSPITAL OR PSYCHIATRIC UNIT LICENSED UNDER SECTION 137, PURSUANT TO MCL 330.1100.

(~~dd~~AA) "Psychiatrist" means~~ a physician who devotes a substantial portion of his/her time to the practice of psychiatry and who has practiced psychiatry for 1 year immediately preceding certification by him/her of any individual under the Mental Health Code, as defined by R330.1001(1)(l)~~ 1 OR MORE OF THE FOLLOWING, PURSUANT TO MCL 330.1100:

~~.~~ (I) A PHYSICIAN WHO HAS COMPLETED A RESIDENCY PROGRAM IN PSYCHIATRY APROVED BY THE ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION OR THE AMERICAN OSTEOPATHIC ASSOCIATION, OR WHO HAS COMPLETED 12 MONTHS OF PSYCHIATRIC ROTATION AND IS ENROLLED IN AN APPROVED RESIDENCY PROGRAM;

(II) A PSYCHIATRIST EMPLOYED BY OR UNDER CONTRACT WITH THE DEPARTMENT OR A COMMUNITY HEALTH SERVICES PROGRAM ON MARCH 28, 1996;

(III) A PHYSICIAN WHO DEVOTES A SUBSTANTIAL PORTION OF HIS OR HER TIME TO THE PRACTICE OF PSYCHIATRY AND IS APPROVED BY THE DIRECTOR.

(~~ee~~BB) "Psychiatric unit" means a unit ~~licensed under the Mental Health Code as defined in R330.1201~~OF A GENERAL HOSPITAL THAT PROVIDES INPATIENT SERVICES FOR INDIVIDUALS WITH SERIOUS MENTAL ILLNESS OR SERIOUS EMOTIONAL DISTURBANCES PURSUANT TO MCL 330.1100.

(~~ff~~CC) "Psychologist" means~~, except in Part 4 of the administrative rules for the Michigan Department of Mental Health, which is subject to the definition in Section 400 of the Mental Health Code, a person who is granted a full or limited license to practice psychology under Part 182 of Act No. 368 of the Public Acts of 1978, as amended, being Section 333.18201 et seq. of the Michigan Compiled Laws~~ AN INDIVIDUAL LICENSED TO ENGAGE IN THE PRACTICE OF PSYCHOLOGY, WHO DEVOTES A SUBSTANTIAL PORTION OF HIS OR HER TIME TO THE DIAGNOSIS AND TREATMENT OF INDIVIDUALS WITH SERIOUS MENTAL ILLNESS, SERIOUS EMOTIONAL DISTURBANCE, OR DEVELOPMENTAL DISABILITY, PURSUANT TO MCL 333.16101 TO 333.18838.

(~~gg~~DD) "Public patient" means an individual approved for mental health services by a CMH or an individual who is admitted as a patient under Section 423, 429, or 438 of the Mental Health Code, Act No. 258 of the Public Acts of 1974, being Sections 330.1423, 330.1429, and 330.1438 of the Michigan Compiled Laws.

(~~hh~~EE) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(~~ii~~FF) "Registered professional nurse" or "R.N." means an individual licensed IN MICHIGAN PURSUANT TO THE PROVISIONS OF MCL 333.16101 TO 333.18838~~under Article 15 of the Code, being Sections 333.17201, et seq. of the Michigan Compiled Laws, to engage in the practice of nursing which scope of practice includes teaching, direction, and supervision of less skilled personnel in the performance of delegated nursing activities~~.

(~~jj~~GG) "Replacement beds" means beds in a psychiatric hospital or unit which meet all of the following conditions:

(i) an equal or greater number of beds are currently licensed to the applicant at the CURRENT licensed site~~ at which the proposed replacement beds are currently licensed~~;

(ii) the beds are proposed for replacement in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, OR OTHER COMPARABLE ARRANGEMENT~~, etc.~~); and

(iii) the beds to be replaced will be located in the replacement zone.

(~~kk~~HH) "Replacement zone" means a proposed licensed site which is:

(i) in the same planning area as the existing licensed site; and

(ii) on the same site, on a contiguous site, or on a site within ~~2~~ 15 miles of the existing licensed site ~~if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000~~.

~~(ll) "Specialized psychiatric program" means an inpatient program for children/adolescents. A specialized psychiatric program will have one or more of the following:~~

~~(i) the program will be represented as providing specialized services to child/adolescent patients;~~

~~(ii) the program has admission criteria and treatment protocols specific to children/adolescents;~~

~~(iii) employees of the specialized psychiatric program will be provided with orientation/in-service training directed at children/adolescents;~~

~~(iv) some or all of the job descriptions that staff the unit require education/experience specific to children/adolescents; or~~

~~(v) the facility will seek a special rate of reimbursement from third party payers for the specialized psychiatric program.~~

(~~mm~~ll) "Social worker" ~~or "certified social worker" or "social work technician"~~ means ~~a~~ AN INDIVIDUAL REGISTERED IN MICHIGAN TO ENGAGE IN SOCIAL WORK UNDER THE PROVISIONS OF MCL 333.18501. ~~person who is so certified pursuant to Act 352 of the Public Acts of 1972, as amended, being Section 338.1751 et seq. of the Michigan Compiled Laws~~.

(2) The terms defined in the Code have the same meanings when used in these standards.

Section 3. Determination of needed Inpatient psychiatric bed supply

Sec. 3. (1) Until changed by the Commission in accordance with Section 4(3) and Section 5, the use rate for the base year for the population age 0-17 is set forth in Appendix D.

(2) The number of child/adolescent inpatient psychiatric beds needed in a planning area shall be determined by the following formula:

(a) Determine the population for the planning year for each separate planning area for the population age 0-17.

(b) Multiply the population by the use rate established in Appendix D. The resultant figure is the total patient days.

(c) Divide the total patient days obtained in subsection (b) by 365 (or 366 for leap years) to obtain the projected average daily census (ADC).

(d) Divide the ADC by 0.75.

~~(e) The number determined in subsection (d) represents the number of child/adolescent inpatient psychiatric beds needed in a planning area for the planning year.~~

(E) FOR EACH PLANNING AREA, ALL PSYCHIATRIC HOSPITALS OR UNITS WITH AN AVERAGE OCCUPANCY OF 60% OR LESS FOR THE PREVIOUS 24 MONTHS WILL HAVE THE ADC, FOR THE PREVIOUS 24 MONTHS, MULTIPLIED BY 1.7. THE NET DECREASE FROM THE CURRENT LICENSED BEDS WILL GIVE THE NUMBER TO BE ADDED TO THE BED NEED.

(F) THE ADJUSTED BED NEED FOR THE PLANNING AREA IS THE SUM OF THE RESULTS OF SUBSECTIONS (D) AND (E).

(3) The number of needed adult inpatient psychiatric beds shall be determined by multiplying the population aged 18 years and older for the planning year for each planning area by the either:

(a) The ratio of adult beds per 10,000 adult population set forth in Appendix C; or

(b) The statewide ratio of adult beds per 10,000 adult population set forth in Appendix C, whichever is lower; and dividing the result by 10,000. If the ratio set forth in Appendix C for a specific planning area is "0", the statewide ratio of adult beds per 10,000 adult population shall be used to determine the number of needed adult inpatient psychiatric beds.

(C) FOR EACH PLANNING AREA, AN ADDITION TO THE BED NEED WILL BE MADE FOR LOW OCCUPANCY FACILTIES. ALL PSYCHIATRIC HOSPITALS OR UNITS WITH AN AVERAGE OCCUPANCY OF 60% OR LESS FOR THE PREVIOUS 24 MONTHS WILL HAVE THE ADC, FOR THE

PREVIOUS 24 MONTHS, MULTIPLIED BY 1.5. THE NET DECREASE FROM THE CURRENT LICENSED BEDS WILL GIVE THE NUMBER TO BE ADDED TO THE BED NEED.

(D) THE ADJUSTED BED NEED FOR THE PLANNING AREA IS THE SUM OF THE RESULTS OF SUBSECTIONS (B) AND (C).

Section 4. Bed Need for Inpatient Psychiatric Beds

Sec. 4. (1) For purposes of these standards, until otherwise changed by the Commission, the bed need numbers determined pursuant to Section 3, incorporated as part of these standards as Appendices A and B, as applicable, shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The ~~Commission may direct the~~ Department SHALL ~~to~~ apply the bed need methodologies in Section 3 ON A BIENNIAL BASIS.

(3) The Commission shall designate the planning year, and, for child/adolescent beds, the base year, which shall be utilized in applying the bed need methodologies pursuant to subsection (2).

(4) ~~When directed by the Commission to apply the methodologies pursuant to subsection (2), the~~ THE effective date of the bed need numbers shall be established by the Commission.

(5) New bed need numbers established by subsections (2) and (3) shall supercede the bed need numbers shown in Appendices A and B and shall be included as amended appendices to these standards.

(6) Modifications made by the Commission pursuant to this section shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. Modification of the Child/adolescent use rate by changing the base year

Sec. 5. (1) The Commission may modify the base year based on data obtained from the Department and presented to the Commission. The Department shall calculate the use rate for the population age 0-17 and biennially present the revised use rate based on the most recent base year information available biennially to the CON Commission.

(2) The Commission shall establish the effective date of the modifications made pursuant to subsection (1).

(3) Modifications made by the Commission pursuant to subsection (1) shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 6. Requirements for approval ~~for all applicants~~TO INTIATE SERVICE

Sec. 6. ~~(1)(a)~~ An applicant proposing ~~either:~~ THE INITIATION OF AN ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE SHALL DEMONSTRATE OR PROVIDE THE FOLLOWING:

(1) THE NUMBER OF BEDS PROPOSED IN THE CON APPLICATION CAN NOT RESULT IN THE NUMBER OF EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC BEDS, AS APPLICABLE, IN THE PLANNING AREA EXCEEDING THE BED NEED SET FORTH IN APPENDIX A OR B, AS APPLICABLE. HOWEVER, AN APPLICANT MAY REQUEST AND BE APPROVED FOR UP TO A MAXIMUM OF 10 BEDS IF, WHEN THE TOTAL NUMBER OF EXISTING ADULT BEDS OR EXISTING

CHILD/ADOLESCENT BEDS IS SUBTRACTED FROM THE BED NEED FOR THE PLANNING AREA SET FORTH IN APPENDIX A OR B, THE DIFFERENCE IS EQUAL TO OR MORE THAN 1 OR LESS THAN 10.

(2) A WRITTEN RECOMMENDATION, FROM THE DEPARTMENT OR THE CMH THAT SERVES THE COUNTY IN WHICH THE PROPOSED BEDS OR SERVICE WILL BE LOCATED, WHICH SHALL INCLUDE AN AGREEMENT TO ENTER INTO A CONTRACT TO MEET THE NEEDS OF THE PUBLIC PATIENT. AT A MINIMUM, THE LETTER OF AGREEMENT SHALL SPECIFY THE NUMBER OF BEDS TO BE ALLOCATED TO THE PUBLIC PATIENT AND THE APPLICANT'S INTENTION TO SERVE PATIENTS WITH AN INVOLUNTARY COMMITMENT STATUS.

(3) THE NUMBER OF BEDS PROPOSED IN THE CON APPLICATION TO BE ALLOCATED FOR USE BY PUBLIC PATIENTS SHALL NOT BE LESS THAN 50% OF THE BEDS PROPOSED IN THE CON APPLICATION. APPLICATIONS PROPOSED IN DIRECT RESPONSE TO A DEPARTMENT PLAN PURSUANT TO SUBSECTION (5) SHALL ALLOCATE NOT LESS THAN 80% OF THE BEDS PROPOSED IN THE CON APPLICATION.

(4) THE MINIMUM NUMBER OF BEDS IN A PSYCHIATRIC UNIT SHALL BE AT LEAST 10 BEDS. IF A PSYCHIATRIC UNIT HAS OR PROPOSES TO OPERATE BOTH ADULT AND CHILD/ADOLESCENT BEDS, EACH UNIT SHALL HAVE A MINIMUM OF 10 BEDS. THE DEPARTMENT MAY APPROVE AN APPLICATION FOR A UNIT OF LESS THAN 10 BEDS, IF THE APPLICANT DEMONSTRATES TO THE SATISFACTION OF THE DEPARTMENT, THAT TRAVEL TIME TO EXISTING UNITS WOULD SIGNIFICANTLY LIMIT ACCESS TO CARE.

(5) AN APPLICANT SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1) IF THE APPLICANT DEMONSTRATES THAT THE APPLICATION MEETS BOTH OF THE FOLLOWING:
(A) THE DIRECTOR OF THE DEPARTMENT DETERMINES THAT AN EXCEPTION TO SUBSECTION (1) SHOULD BE MADE AND CERTIFIES IN WRITING THAT THE PROPOSED PROJECT IS A DIRECT RESPONSE TO A DEPARTMENT PLAN FOR REDUCING THE USE OF PUBLIC INSTITUTIONS FOR ACUTE MENTAL HEALTH CARE THROUGH THE CLOSURE OF A STATE-OWNED PSYCHIATRIC HOSPITAL; AND
(B)THE PROPOSED BEDS WILL BE LOCATED IN THE AREA CURRENTLY SERVED BY THE PUBLIC INSTITUTION THAT WILL BE CLOSED, AS DETERMINED BY THE DEPARTMENT.

~~(i) an increase in the number of licensed psychiatric beds;~~
~~(ii) the initiation or expansion of a child/adolescent specialized psychiatric program; or~~
~~(iii) the replacement of licensed psychiatric beds, shall demonstrate that the Department, pursuant to Section 134 of the Mental Health Code being Section 330.1134 of the Michigan Compiled Laws, recommends approval of the proposed project.~~
~~(b) The Department's recommendation shall be in writing and based on all of the following, as applicable:~~
~~(i) the applicant's compliance with all applicable CON review standards;~~
~~(ii) the recommendation of the local CON review agency, if any, if the recommendation is received in accordance with the time lines set forth in the CON administrative rules; and~~
~~(iii) the written recommendation from the CMH(s) that serves the planning area in which the proposed beds or services will be located, or a majority of the boards if more than one CMH serves the planning area in which the proposed beds or services will be located. If the applicant is a CMH, the Department's recommendation shall not be based on that CMHs recommendation.~~

~~(2) An applicant proposing either an increase in the number of licensed psychiatric beds or the initiation or expansion of a specialized psychiatric program for children/adolescents shall demonstrate each of the following:~~

~~(a) The number of beds proposed in the CON application to be allocated for use by public patients shall not be less than 50 percent (50%) of the beds proposed in the CON application. Applications proposed in direct response to a Department plan pursuant to subsection (e) or (g) shall allocate not less than 80 percent (80%) of the beds proposed in the CON application.~~

~~(b) Previously made commitments, if any, to the Department or CMH(s) to serve public patients have been fulfilled.~~

~~(c) The applicant has, at the time the application is deemed submitted, a signed letter of agreement, with the Department or the CMH(s) serving the planning area in which the proposed beds or services will be located, to enter into a contract with the CMH(s) or the Department to meet the needs of the public patient when the proposed beds or services become operational. At a minimum, the letter of agreement shall specify the number of beds to be allocated to the public patient and the applicant's intention to serve patients with an involuntary commitment status.~~

~~(d) In the case of an applicant that is proposing an increase in the number of licensed psychiatric beds at an existing facility, the average occupancy rate for all existing beds, as applicable, in all psychiatric hospitals or units in the planning area in which the proposed beds or services will be located, was at least 85 percent (85%) for adult beds and 75% for child/adolescent beds, for the 12 month period immediately preceding the date the application was deemed submitted based on the Department's data.~~

~~(e) Subsection (d) shall not apply if the Director of the Department has certified in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital.~~

~~(f) If approved, the number of beds proposed in the CON application will not result in the number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area exceeding the needed bed supply set forth in Appendix A or B, as applicable. However, an applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing adult beds" or existing child/adolescent beds" is subtracted from the bed need for the planning area set forth in Appendix B, the difference is equal to or more than 1 or less than 20.~~

~~(g) An applicant shall not be required to be in compliance with subsection (f) if the applicant demonstrates that the application meets both of the following:~~

~~(i) the Director of the Department determines that an exception to subsection (f) should be made and certifies in writing the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital; and~~

~~(ii) the proposed beds will be located in the area currently served by the public institution that will be closed, as determined by the Department.~~

~~(3) The minimum number of beds in a psychiatric unit in a general hospital shall be at least 20 beds. If a psychiatric unit has or proposes to operate both adult and child/adolescent beds, then each unit shall have a minimum of 20 beds. The Department may approve an application for a unit of less than 20 beds, if the applicant demonstrates, to the satisfaction of the Department, that travel time to existing units would significantly impair access to care.~~

~~(4) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is a new provider not currently enrolled in Medicaid shall provide a signed affidavit stating that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.~~

~~**Section 7. Requirements for approval for applicants requesting a specialized psychiatric program for children/adolescents**~~

~~Sec. 7. An applicant proposing to use inpatient psychiatric beds (including new, additional, replacement or converted beds) for a specialized psychiatric program for children/adolescents shall~~

~~demonstrate that it meets all of the following:~~
~~(a) The proposed project meets the requirements of Section 6 of these standards, as applicable.~~
~~(b) The proposed specialized psychiatric program for children/adolescents shall be physically distinct from other inpatient units and shall provide a minimum of 40 gross square feet per child/adolescent bed.~~
~~(c) The proposed specialized psychiatric program for children/adolescents shall provide a dedicated group therapy area consisting of either:~~
~~(i) a room of at least 225 gross square feet; or~~
~~(ii) a minimum of 8 gross square feet per child/adolescent bed.~~
~~(d) The proposed specialized psychiatric program for children/adolescents shall comply with Rules 330.1239 and 330.1243 of the Department of Mental Health administrative rules.~~
~~(e) The proposed specialized psychiatric program for children/adolescents shall provide the following dedicated educational/classroom space:~~
~~(i) a room of at least 325 gross square feet, or the minimum square footage per licensed child/adolescent bed as required per student by the home school district's standards for special education classrooms, whichever is less; and~~
~~(ii) one dedicated educational/vocational training area for every 16 licensed child/adolescent beds.~~

SECTION 7. REQUIREMENTS FOR APPROVAL TO INCREASE BEDS

SEC. 7 AN APPLICANT PROPOSING AN INCREASE IN THE NUMBER OF ADULT OR CHILD/ADOLESCENT BEDS SHALL DEMONSTRATE OR PROVIDE THE FOLLOWING:

(1) THE NUMBER OF BEDS PROPOSED IN THE CON APPLICATION WILL NOT RESULT IN THE NUMBER OF EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC BEDS, AS APPLICABLE, IN THE PLANNING AREA EXCEEDING THE BED NEED SET FORTH IN APPENDIX A OR B, AS APPLICABLE. HOWEVER, AN APPLICANT MAY REQUEST AND BE APPROVED FOR UP TO A MAXIMUM OF 10 BEDS IF, WHEN THE TOTAL NUMBER OF EXISTING ADULT BEDS OR EXISTING CHILD/ADOLESCENT BEDS IS SUBTRACTED FROM THE BED NEED FOR THE PLANNING AREA SET FORTH IN APPENDIX A OR B, THE DIFFERENCE IS EQUAL TO OR MORE THAN 1 OR LESS THAN 10.

(2) THE AVERAGE OCCUPANCY RATE FOR THE APPLICANT'S FACILITY, WHERE THE PROPOSED BEDS ARE TO BE LOCATED, WAS AT LEAST 70% FOR ADULT OR CHILD/ADOLESCENT BEDS, AS APPLICABLE, DURING THE MOST RECENT, CONSECUTIVE 24-MONTH PERIOD, AS OF THE DATE OF THE SUBMISSION OF THE APPLICATION, FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.

(3) SUBSECTIONS (1) AND (2) SHALL NOT APPLY IF THE APPLICANT MEETS THE FOLLOWING:
(I) THE BEDS ARE BEING ADDED AT THE EXISTING LICENSED SITE;
(II) THE AVERAGE OCCUPANY RATE FOR THE APPLICANT'S FACILITY WAS AT LEAST 75% FOR FACILITIES WITH 19 BEDS OR LESS AND 80% FOR FACILITIES WITH 20 BEDS OR MORE, AS APPLICABLE, DURING THE MOST RECENT, CONSECUTIVE 24-MONTH PERIOD, AS OF THE DATE OF THE SUBMISSION OF THE APPLICATION, FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.
(III) THE NUMBER OF BEDS BEING ADDED SHALL NOT EXCEED THE RESULTS OF THE FOLLOWING FORMULA: THE FACILITY'S AVERAGE DAILY CENSUS FOR THE MOST RECENT, CONSECUTIVE 24-MONTH PERIOD, AS OF THE DATE OF THE SUBMISSION OF THE APPLICATION, FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT MULTIPLIED BY 1.5 FOR ADULT BEDS AND 1.7 FOR CHILD/ADOLESCENT BEDS.

(4) PROOF OF CURRENT CONTRACT OR DOCUMENTATION OF CONTRACT RENEWAL, IF CURRENT CONTRACT IS UNDER NEGOTATION, WITH AT LEAST ONE CMH OR ITS DESIGNEE THAT SERVES THE PLANNING AREA IN WHICH THE PROPOSED BEDS OR SERVICE WILL BE

LOCATED.

(5) PREVIOUSLY MADE COMMITMENTS, IF ANY, TO THE DEPARTMENT OR CMH TO SERVE PUBLIC PATIENTS HAVE BEEN FULFILLED.

(6) THE NUMBER OF BEDS PROPOSED IN THE CON APPLICATION TO BE ALLOCATED FOR USE BY PUBLIC PATIENTS SHALL NOT BE LESS THAN 50% OF THE BEDS PROPOSED IN THE CON APPLICATION. APPLICATIONS PROPOSED IN DIRECT RESPONSE TO A DEPARTMENT PLAN PURSUANT TO SUBSECTION (9) SHALL ALLOCATE NOT LESS THAN 80% OF THE BEDS PROPOSED IN THE CON APPLICATION.

(7) THE MINIMUM NUMBER OF BEDS IN A PSYCHIATRIC UNIT SHALL BE AT LEAST 10 BEDS. IF A PSYCHIATRIC UNIT HAS OR PROPOSES TO OPERATE BOTH ADULT AND CHILD/ADOLESCENT BEDS, THEN EACH UNIT SHALL HAVE A MINIMUM OF 10 BEDS. THE DEPARTMENT MAY APPROVE AN APPLICATION FOR A UNIT OF LESS THAN 10 BEDS, IF THE APPLICANT DEMONSTRATES, TO THE SATISFACTION OF THE DEPARTMENT, THAT TRAVEL TIME TO EXISTING UNITS WOULD SIGNIFICANTLY IMPAIR ACCESS TO CARE.

(8) SUBSECTION (2) SHALL NOT APPLY IF THE DIRECTOR OF THE DEPARTMENT HAS CERTIFIED IN WRITING THAT THE PROPOSED PROJECT IS A DIRECT RESPONSE TO A DEPARTMENT PLAN FOR REDUCING THE USE OF PUBLIC INSTITUTIONS FOR ACUTE MENTAL HEALTH CARE THROUGH THE CLOSURE OF A STATE-OWNED PSYCHIATRIC HOSPITAL.

(9) AN APPLICANT SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1) IF THE APPLICANT DEMONSTRATES THAT THE APPLICATION MEETS BOTH OF THE FOLLOWING:
(A) THE DIRECTOR OF THE DEPARTMENT DETERMINES THAT AN EXCEPTION TO SUBSECTION (1) SHOULD BE MADE AND CERTIFIES IN WRITING THAT THE PROPOSED PROJECT IS A DIRECT RESPONSE TO A DEPARTMENT PLAN FOR REDUCING THE USE OF PUBLIC INSTITUTIONS FOR ACUTE MENTAL HEALTH CARE THROUGH THE CLOSURE OF A STATE-OWNED PSYCHIATRIC HOSPITAL; AND
(B)THE PROPOSED BEDS WILL BE LOCATED IN THE AREA CURRENTLY SERVED BY THE PUBLIC INSTITUTION THAT WILL BE CLOSED AS DETERMINED BY THE DEPARTMENT.

Section 8. Requirements for approval ~~--~~ FOR replacement beds

Sec. 8. An applicant proposing replacement beds shall not be required to be in compliance with the needed bed supply set forth in Appendix A or B, as applicable, if the applicant demonstrates all of the following:

(~~a~~1) The project proposes to replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently located.

(~~b~~2) The proposed licensed site is in the replacement zone.

(~~c~~3) The applicant meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(~~d~~4) Not less than 50% ~~percent (50%)~~ of the beds proposed to be replaced shall be allocated for use by public patients.

(~~e~~5) Previously made commitments, if any, to the Department or CMH~~(s)~~ to serve public patients have been fulfilled.

(~~f~~6) ~~The applicant has, at the time the application is deemed submitted, a signed letter of agreement,~~

~~with the Department or the CMH(s) that serve the planning area in which the beds are located, to enter into a contract with the CMH(s) or the Department to meet the needs of the public patient when the proposed replacement beds are licensed for use. At a minimum, the letter of agreement shall specify the number of beds to be allocated to the public patient and the applicant's intention to serve patients with an involuntary commitment status.~~ PROOF OF CURRENT CONTRACT OR DOCUMENTATION OF CONTRACT RENEWAL, IF CURRENT CONTRACT IS UNDER NEGOTATION, WITH THE CMH OR ITS DESIGNEE THAT SERVES THE PLANNING AREA IN WHICH THE PROPOSED BEDS OR SERVICE WILL BE LOCATED.

Section 9. Requirements for approval ~~--~~FOR acquisition of a psychiatric hospital or unit

Sec. 9. An applicant proposing to acquire a psychiatric hospital or unit shall not be required to be in compliance with the needed bed supply set forth in Appendix A or B, as applicable, for the planning area in which the psychiatric hospital or unit subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(~~a~~1) The acquisition will not result in a change in the number of licensed beds or beds designated for a child/adolescent specialized psychiatric program.

(~~b~~2) The licensed site does not change as a result of the acquisition.

~~(c) The project is limited solely to the acquisition of a psychiatric hospital or unit.~~

Section 10. Additional requirements for applications included in Comparative review

Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code being Section 333.22229 of the Michigan Compiled Laws or these standards shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative review.

(2) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, ~~being Section 333.22225(1) of the Michigan Compiled Laws,~~ and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not exceed the need, ~~as defined in Section 22225(1),~~ in the order in which the applications were received by the Department, based on the date and time stamp placed on the applicationS ~~for CON form (form T-150-G-1.01 or any subsequent replacement form)~~ by the ~~Division of Health Facility Development (or the administrative unit of the~~ Department ~~responsible for administering the CON program) when the application is filed~~ IN ACCORDANCE WITH RULE 325.9123.

(3)(a) A qualifying project application will be awarded 5 points if, within six months of beginning operation and annually thereafter, 100% of the licensed psychiatric beds (both existing and proposed) at the facility will be Medicaid certified.

(b) A qualifying project will have 4 points deducted if, on or after November 26, 1995, the records maintained by the Department document that the applicant was required to enter into a contract with either the Department or a CMH to serve the public patient and did not do so.

(c) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records maintained by the Department document that the applicant entered into a contract with MDCH or CMH but never admitted any public patients referred pursuant to that contract.

(d) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records maintained by the Department document that an applicant agreed to serve patients with an involuntary commitment status but has not admitted any patients referred with an involuntary commitment status.

~~(e) A qualifying project will be awarded 3 points if the applicant agrees to enter into a unified agreement within 6 months of beginning operation of the beds or specialized psychiatric program. A unified agreement is defined as an agreement among at least the following entities: the Michigan Department of Human Services, the home school district(s), the juvenile division of the probate court and the CMH(s) serving the planning area in which the proposed beds will be located, or a majority of the boards, if more than one CMH serves the planning area in which the proposed beds will be located.~~

(~~f~~E) A qualifying project will be awarded 3 points if the applicant presents, in its application, a plan, acceptable to the Department, for the treatment of patients requiring long-term treatment. For purposes of this subsection, long-term treatment is defined to mean an inpatient length of stay in excess of 45 days.

(~~g~~F) A qualifying project will be awarded 3 points if the applicant CURRENTLY PROVIDES A PARTIAL HOSPITALIZATION PSYCHIATRIC PROGRAM, OUTPATIENT PSYCHIATRIC SERVICES, OR PSYCHIATRIC AFTERCARE SERVICES, OR THE APPLICANT INCLUDES ANY OF THESE SERVICES AS PART OF THEIR PROPOSED PROJECT, AS DEMONSTRATED BY SITE PLANS AND SERVICE CONTRACTS. ~~agrees that within 6 months of beginning operation of the proposed beds or specialized psychiatric program, the applicant shall offer, either directly or through written agreement with another provider(s), a comprehensive array of services. For purposes of this subsection, a comprehensive array of services is defined to include but not be limited to: a partial hospitalization psychiatric program, outpatient services, and aftercare services.~~

(h) A qualifying project will have 4 points deducted if the Department has issued, within three years prior to the date on which the CON application was deemed submitted, a temporary permit or provisional license due to a pattern of licensure deficiencies at any psychiatric hospital or unit owned or operated by the applicant in this state.

(i) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

Hospital Indigent Volume	Points Awarded
0 - <6%	1
6 - <11%	2
11 - <16%	3
16 - <21%	4
21 - <26%	5
26 - <31%	6
31 - <36%	7
36 - <41%	8
41 - <46%	9
46% +	10

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Department pursuant to Chapter VIII of the Medical Assistance Program manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(j) A qualifying project will have points deducted based on the applicant's record of compliance with applicable safety and operating standards for any psychiatric hospital or unit owned and/or operated by the applicant in this state. Points shall be deducted in accordance with the following schedule if, on or after November 26, 1995, the Department records document any non-renewal or revocation of license for cause or non-renewal or termination of certification for cause of any psychiatric hospital or unit owned or operated by the applicant in this state.

Psychiatric Hospital/Unit Compliance Action	Points Deducted
Non-renewal or revocation of license	4
Non-renewal or termination of:	
Certification - Medicare	4
Certification - Medicaid	4

(4) ~~No~~ THE MINIMUM NUMBER OF points will be awarded to an applicant under THE individual subsections of THIS Section ~~10~~ FOR ~~if~~ CONFLICTING information presented in THIS Section ~~10~~ AND ~~is inconsistent with~~ related information provided in other sections of the CON application.

SECTION 11. REQUIREMENTS FOR APPROVAL FOR ALL APPLICANTS

SEC. 11 AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.

Section ~~11~~12. Project delivery requirements - terms of approval for all applicants

Sec. ~~11~~12. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards in the Mental Health Code or the administrative rules promulgated thereunder.

(~~c~~) Compliance with the following applicable quality assurance standards:

(i) The average occupancy rate for all licensed beds at the psychiatric hospital or unit shall be at least ~~85~~ 60 percent (%) for adult beds and ~~75~~ 40 percent (%) for child/adolescent beds for the second 12 months of operation, and annually thereafter. AFTER THE SECOND 12 MONTHS OF OPERATION, IF THE AVERAGE OCCUPANCY RATE IS BELOW 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS, THE NUMBER OF BEDS SHALL BE REDUCED TO ACHIEVE A MINIMUM OF 60% AVERAGE ANNUAL OCCUPANCY FOR ADULT BEDS OR 40% ANNUAL AVERAGE OCCUPANCY FOR CHILD/ADOLESCENT BEDS FOR THE REVISED LICENSED BED COMPLEMENT. HOWEVER, THE PSYCHIATRIC HOSPITAL OR UNIT SHALL NOT BE REDUCED TO LESS THAN 10 BEDS.

(ii) The proposed licensed psychiatric beds shall be operated in a manner that is appropriate for a population with the ethnic, socioeconomic, and demographic characteristics including the developmental stage of the population to be served.

(iii) The applicant shall establish procedures to care for patients who are disruptive, combative, or suicidal and for those awaiting commitment hearings, and the applicant shall establish a procedure for obtaining physician certification necessary to seek an order for involuntary treatment for those persons that, in the judgment of the professional staff, meet the Mental Health Code criteria for involuntary treatment.

(iv) The applicant shall develop a standard procedure for determining, at the time the patient first presents himself or herself for admission or within 24 hours after admission, whether an alternative to inpatient psychiatric treatment is appropriate.

(v) The inpatient psychiatric hospital or unit shall provide clinical, administrative, and support services that will be at a level sufficient to accommodate patient needs and volume, and will be provided seven days a week to assure continuity of services and the capacity to deal with emergency admissions.

(vi) The applicant shall participate in a data collection network established and administered by the

Department or its designee. The data may include, but is not limited to: annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(vii) The applicant shall provide the Department with a notice stating the date the beds or services are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(viii) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) not deny acute inpatient mental health services to any individual based on ability to pay, source of payment, age, race, handicap, national origin, religion, gender, sexual orientation or commitment status;

(B) provide acute inpatient mental health services to any individual based on clinical indications of need for the services;

(C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(ix) An applicant required to enter into a contract with a CMH(s) or the Department pursuant to these standards shall have in place, at the time the approved beds or services become operational, a signed contract to serve the public patient. The contract must address a single entry and exit system including discharge planning for each public patient. The contract shall specify that at least 50% or 80% of the approved beds, as required by the applicable sections of these standards, shall be allocated to the public patient, and shall specify the hospital's or unit's willingness to admit patients with an involuntary commitment status. The contract need not be funded.

(x) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(2) Compliance with THIS Section ~~11~~ shall be determined by the Department based on a report submitted by the applicant and/or other information available to the Department.

(3) The agreements and assurances required by THIS Section ~~11~~ shall be in the form of a certification AGREED TO BY THE ~~authorized by the governing body of the~~ applicant or its authorized agent.

Section ~~12~~13. Project delivery requirements - additional terms of approval for child/adolescent ~~specialized psychiatric programs~~ SERVICE

Sec. ~~12~~13. (1) In addition to the provisions of Section ~~11~~12, an applicant for a child/adolescent SERVICE ~~specialized psychiatric program~~ shall agree to operate the program in compliance with the following terms of CON approval, as applicable:

(a) There shall be at least the following child and adolescent mental health professionals employed, either directly or by contract, by the hospital or unit, each of whom must have been involved in the delivery of child/adolescent mental health services for at least 2 years within the most recent 5 years:

(i) a child/adolescent psychiatrist;

(ii) a child psychologist;

(iii) a psychiatric nurse;

(iv) a psychiatric social worker;

(v) an occupational therapist or recreational therapist; and

~~(vi) a special education teacher (certified with emotionally impaired).~~

(b) There shall be a recipient rights officer employed by the hospital or the program.

(c) The applicant shall identify a staff member(s) whose assigned responsibilities include discharge planning and liaison activities with the home school district(s).

(d) There shall be the following minimum staff employed either on a full time basis or on a consulting

basis:

(i) a pediatrician;

(ii) a child neurologist;

(iii) a neuropsychologist;

(iv) a speech and language therapist;

(v) an audiologist; and

(vi) a dietician.

(e) A child/adolescent ~~specialized psychiatric program~~ SERVICE shall have the capability to determine that each inpatient admission is the appropriate treatment alternative consistent with Section 498e of the Mental Health Code, being Section 330.1498e of the Michigan Compiled Laws.

(f) The child/adolescent ~~specialized psychiatric program~~ SERVICE shall develop and maintain a coordinated relationship with the home school district of any patient to ensure that all public education requirements are met.

(g) The applicant shall demonstrate that the child/adolescent ~~specialized psychiatric program~~ SERVICE is integrated within the continuum of mental health services available in its planning area by establishing a formal agreement with the CMH(s) serving the planning area in which the child/adolescent specialized psychiatric program is located. The agreement shall address admission and discharge planning issues which include, at a minimum, specific procedures for referrals for appropriate community services and for the exchange of information with the CMH(s), the probate court(s), the home school district, the Michigan Department of Human Services, the parent(s) or legal guardian(s) and/or the patient's attending physician.

(2) Compliance with THIS Section ~~12~~ shall be determined by the Department based on a report submitted by the program and/or other information available to the Department.

(3) The agreements and assurances required by THIS Section ~~12~~ shall be in the form of a certification AGREED TO BY THE ~~authorized by the governing body of the~~ applicant or its authorized agent.

Section ~~13~~14. Department inventory of beds

Sec. ~~13~~14. The Department shall maintain, and provide on request, a listing of the Department Inventory of Beds for each adult and child/adolescent planning area.

Section ~~14~~15. Planning areas

Sec. ~~14~~15. ~~(1)~~ The planning areas for ~~child/adolescent~~ inpatient psychiatric beds are the geographic boundaries of the groups of counties as follows.

~~**Child/Adolescent**~~

Planning Areas	**Counties**
1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
5	Genesee, Lapeer, Shiawassee
6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland,

	Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford
8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

~~(2) The planning areas for adult inpatient psychiatric beds are the geographic boundaries of the groups of counties as follows.~~

~~**Adult Planning Areas**~~	~~**Counties**~~
~~Detroit/Wayne~~	~~Wayne~~
~~Livingston~~	~~Livingston~~
~~Macomb~~	~~Macomb~~
~~Monroe~~	~~Monroe~~
~~Oakland~~	~~Oakland~~
~~St. Clair~~	~~St. Clair~~
~~Washtenaw~~	~~Washtenaw~~
~~Clinton-Eaton-Ingham~~	~~Clinton, Eaton, Ingham~~
~~Jackson-Hillsdale~~	~~Jackson, Hillsdale~~
~~Lenawee~~	~~Lenawee~~
~~Barry~~	~~Barry~~
~~Berrien~~	~~Berrien~~
~~Branch~~	~~Branch~~
~~Calhoun~~	~~Calhoun~~
~~Cass~~	~~Cass~~
~~Kalamazoo~~	~~Kalamazoo~~
~~St. Joseph~~	~~St. Joseph~~
~~Van Buren~~	~~Van Buren~~
~~**Adult Planning Areas**~~	~~**Counties**~~
~~Allegan~~	~~Allegan~~
~~Ionia~~	~~Ionia~~
~~West Michigan - Kent~~	~~Kent~~
~~West Michigan~~	~~Lake, Mason, Oceana~~
~~Montcalm~~	~~Montcalm~~
~~Muskegon~~	~~Muskegon~~
~~Newaygo~~	~~Newaygo~~
~~Ottawa~~	~~Ottawa~~
~~Genesee~~	~~Genesee~~
~~Lapeer~~	~~Lapeer~~
~~Shiawassee~~	~~Shiawassee~~
~~AuSable Valley~~	~~Iosco, Ogemaw, Oscoda~~
~~Bay-Arenac~~	~~Arenac, Bay~~
~~Central Michigan~~	~~Clare, Gladwin, Isabella, Mecosta, Midland, Osceola~~
~~Gratiot~~	~~Gratiot~~
~~Huron~~	~~Huron~~
~~Saginaw~~	~~Saginaw~~

~~Sanilac~~	~~Sanilac~~
~~Tuscola~~	~~Tuscola~~
~~North Country~~	~~Antrim, Charlevoix, Cheboygan, Emmet, Kalkaska, Otsego~~
~~Northern Lakes~~	~~Crawford, Grand Traverse, Leelanau, Missaukee, Roscommon, Wexford~~
~~Manistee-Benzie~~	~~Benzie, Manistee~~
~~Northeast Michigan~~	~~Alcona, Alpena, Montmorency, Presque Isle~~
~~Pathways~~	~~Alger, Delta, Luce, Marquette~~
~~Copper Country~~	~~Baraga, Houghton, Keweenaw, Ontonagon~~
~~Northpointe~~	~~Dickinson, Iron, Menominee~~
~~Gogebic~~	~~Gogebic~~
~~Hiawatha~~	~~Chippewa, Mackinac, Schoolcraft~~

Section ~~15~~16. Effect on prior CON review standards; comparative reviews

Sec. ~~15~~16. (1) These CON review standards supercede and replace the CON Review Standards for Psychiatric Beds and Services, approved by the CON Commission on ~~March 8~~ JUNE 22, 2005 and effective on ~~May 27~~ OCTOBER 17, 2005.

(2) Projects involving replacement beds OR AN INCREASE IN BEDS, APPROVED PURSUANT TO SECTION 7(3), ARE reviewed under these standards AND shall not be subject to comparative review.

(3) ~~Projects reviewed under these standards involving either: (a) an increase in the number of licensed psychiatric beds, or (b) an increase in the number of beds (whether new, additional, replacement or converted) for a specialized psychiatric program for children/adolescents shall be subject to comparative review.~~ PROJECTS INVOLVING INITIATION OF SERVICE OR AN INCREASE IN BEDS, APPROVED PURSUANT TO SECTION 7(1), ARE REVIEWED UNDER THESE STANDARDS AND SHALL BE SUBJECT TO COMPARATIVE REVIEW.

APPENDIX A

CON REVIEW STANDARDS FOR CHILD/ADOLESCENT PSYCHIATRIC BEDS

The bed need numbers, for purposes of these standards until otherwise changed by the Commission, are as follows:

Planning Area	Bed Need
1	82
2	23
3	14
4	25
5	11
6	14
7	7
8	5
TOTAL	181

APPENDIX B

CON REVIEW STANDARDS FOR ADULT PSYCHIATRIC BEDS

The bed need numbers, for purposes of these standards until otherwise changed by the Commission, are as follows:

~~Planning Area~~	~~Bed Need~~
~~Detroit-Wayne~~	~~420~~
~~Livingston~~	~~37~~
~~Macomb~~	~~179~~
~~Monroe~~	~~22~~
~~Oakland~~	~~261~~
~~St. Clair~~	~~24~~
~~Washtenaw~~	~~76~~
~~Clinton-Eaton-Ingham~~	~~100~~
~~Jackson-Hillsdale~~	~~41~~
~~Lenawee~~	~~22~~
~~Barry~~	~~13~~
~~Berrien~~	~~27~~
~~Branch~~	~~11~~
~~Calhoun~~	~~30~~
~~Cass~~	~~12~~
~~Kalamazoo~~	~~41~~
~~St. Joseph~~	~~14~~
~~Van Buren~~	~~16~~
~~Allegan~~	~~10~~
~~Ionia~~	~~14~~
~~West Michigan - Kent~~	~~123~~
~~West Michigan (Lake, Mason, Oceana)~~	~~15~~
~~Montcalm~~	~~14~~
~~Muskegon~~	~~28~~
~~Newaygo~~	~~11~~
~~Ottawa~~	~~13~~
~~Genesee~~	~~93~~
~~Lapeer~~	~~20~~
~~Shiawassee~~	~~16~~

APPENDIX B - continued

~~Planning Area~~	~~Bed Need~~
~~Ausable Valley (Iosco, Ogemaw, Oscoda)~~	~~14~~
~~Bay-Arenac~~	~~28~~
~~Central Michigan (Clare, Gladwin, Isabella, Mecosta, Midland, Osceola)~~	~~40~~
~~Gratiot~~	~~10~~
~~Huron~~	~~8~~
~~Saginaw~~	~~28~~
~~Sanilac~~	~~10~~
~~Tuscola~~	~~13~~
~~North Country (Antrim, Charlevoix, Cheboygan, Emmet, Kalkaska, Otsego)~~	~~15~~
~~Northern Lakes (Crawford, Grand Traverse, Leelanau, Missaukee, Roscommon, Wexford)~~	~~15~~
~~Manistee-Benzie~~	~~10~~
~~Northeast Michigan (Alcona, Alpena, Montmorency, Presque Isle)~~	~~16~~
~~Pathways (Alger, Delta, Luce, Marquette)~~	~~28~~
~~Copper Country (Baraga, Houghton, Keweenaw, Ontonagon)~~	~~13~~
~~Northpointe (Dickinson, Iron, Menominee)~~	~~15~~
~~Gogebic~~	~~5~~
~~Hiawatha (Chippewa, Mackinac, Schoolcraft)~~	~~14~~
~~**TOTAL**~~	~~1985~~

PLANNING AREA	BED NEED
1	1019
2	163
3	164
4	228
5	129
6	151
7	56
8	75
TOTAL	1985

APPENDIX C

RATIO OF ADULT INPATIENT PSYCHIATRIC BEDS PER 10,000 ADULT POPULATION

~~Adult Planning Area~~	~~Adult Beds per 10,000 Adult Population~~
~~Detroit/Wayne~~	~~3.5229~~
~~Livingston~~	~~.0~~
~~Macomb~~	~~3.1345~~
~~Monroe~~	~~1.8657~~
~~Oakland~~	~~4.1120~~
~~St. Clair~~	~~1.8192~~
~~Washtenaw~~	~~3.2809~~
~~Clinton-Eaton-Ingham~~	~~3.8835~~
~~Jackson-Hillsdale~~	~~2.5359~~
~~Lenawee~~	~~4.5961~~
~~Barry~~	~~.0~~
~~Berrien~~	~~2.1298~~
~~Branch~~	~~4.5248~~
~~Calhoun~~	~~5.3946~~
~~Cass~~	~~.0~~
~~Kalamazoo~~	~~2.1639~~
~~St. Joseph~~	~~.0~~
~~Van Buren~~	~~2.6127~~
~~Allegan~~	~~1.1147~~
~~Ionia~~	~~.0~~
~~West Michigan - Kent~~	~~3.6049~~
~~West Michigan (Lake, Mason, Oceana)~~	~~2.6730~~
~~Montcalm~~	~~3.4171~~
~~Muskegon~~	~~2.1211~~
~~Newaygo~~	~~4.4659~~
~~Ottawa~~	~~.6605~~
~~Genesee~~	~~3.3307~~
~~Lapeer~~	~~2.4962~~
~~Shiawassee~~	~~2.9550~~

APPENDIX C - continued

~~Adult Planning Area~~	~~Adult Beds per 10,000 Adult Population~~
~~Ausable Valley (Iosco, Ogemaw, Oscoda)~~	~~0~~
~~Bay-Arenac~~	~~2.8763~~
~~Central Michigan (Clare, Gladwin, Isabella, Mecosta, Midland, Osceola)~~	~~1.8484~~
~~Gratiot~~	~~3.6413~~
~~Huron~~	~~0~~
~~Saginaw~~	~~1.7369~~
~~Sanilac~~	~~0~~
~~Tuscola~~	~~0~~
~~North Country (Antrim, Charlevoix, Cheboygan, Emmet, Kalkaska, Otsego)~~	~~1.995~~
~~Northern Lakes (Crawford, Grand Traverse, Leelanau, Missaukee, Roscommon, Wexford)~~	~~.9474~~
~~Manistee-Benzie~~	~~0~~
~~Northeast Michigan (Alcona, Alpena, Montmorency, Presque Isle)~~	~~2.7948~~
~~Pathways (Alger, Delta, Luce, Marquette)~~	~~3.8769~~
~~Copper Country (Baraga, Houghton, Keweenaw, Ontagon)~~	~~0~~
~~Northpointe (Dickinson, Iron, Menominee)~~	~~0~~
~~Gogebic~~	~~0~~
~~Hiawatha (Chippewa, Mackinac, Schoolcraft)~~	~~0~~
~~State~~	~~2.8697~~

PLANNING AREA	ADULT BEDS PER 10,000 ADULT POPULATION
1	
2	
3	
4	
5	
6	
7	
8	
STATE	

APPENDIX D

CON REVIEW STANDARDS
FOR CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS

The use rate per 1000 population age 0-17, for purposes of these standards, until otherwise changed by the Commission, is ~~17.85~~.

Cardiac Catheterization Standards Advisory Committee (CCSAC)

Summary Report

September 18, 2007

Summary Report: Cardiac Catheterization Standards Advisory Committee
Submitted by: Carol L. Joseph, RN; Chairperson

Introduction

The Certificate of Need (CON) Commission created the Cardiac Catheterization Standards Advisory Committee (CCSAC) in January 2007. The committee of fourteen members is comprised of experts in diagnostic and interventional cardiology, consumers, health care purchasers, payers, and providers from across the State of Michigan. The committees' term started on January 24, 2007 and expired on July 24, 2007.

The Committee was charged with the following responsibilities:

1. Review whether facilities providing cardiac catheterization services in Michigan should be required to participate in either or both Blue Cross of Michigan Cardiovascular Consortium (BMC2) registry and the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR)

2. Review and examine minimum physician volume requirements and institutional volume requirements in the Certificate of Need Review Standards for Cardiac Catheterization Services

3. Consider new and emerging technology

4. How to demonstrate need and compliance looking at geographic locations, volume, and types of procedures.

5. Report to the Commission at the December 12, 2006 meeting about any additional priority issues not in the charge.

Six (6) meetings[1] were held during this period. A work plan process was developed prior to the first meeting by the Chairperson and Vice-Chairperson. The work plan was reviewed at the first meeting, other options discussed and a motion was made to accept the work plan for the CCSAC meetings. The plan included the following steps:

- Discovery of current status – February 21,2007
- Benchmarks and best practices – February 21, 2007
- Analyze options – March 29, 2007
- Vetting and testing – April 25, 2007
- Summarize and draft recommendations – May 22, 2007
- Final recommendations – June 20, 2007

Discovery of current status involved requesting information from Mr. Nash regarding the status of data collection and adherence to the current standards for all Michigan cardiac programs,

[1] Meeting dates: 1/24/2007, 2/21/2007, 3/29/2007, 4/25/2007, 5/22/2007 and 6/20/2007.

including both institutional and physician volumes. Data and information from the department also included definitions in the current standards, a map of Michigan with the locations of cardiac catheterization laboratories and open-heart surgery programs, population data including growth patterns and health service areas. The staff was asked to gather information on the number of Michigan programs currently participating in the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) & the Blue Cross of Michigan Cardiovascular Consortium (BMC^2) registry. The staff also was asked to gather outcome data from sources available to the public, including information located on the Center for Medicare Services (CMS) and the Joint Commission of Accreditation of Healthcare Organizations (JCAHO). Additionally the Committee asked the staff to review their files to determine if letters of complaint or concern regarding access to cardiac catheterization had been received in the last 2 years and provide feedback on the issue and location of the access concern.

The Committee members were charged to review the issue paper on "Certificate of Need (CON) Cardiac Catheterization and Open Heart Surgeries Volume Requirements dated June 2005," the 2005 American College of Cardiology (ACC) Guidelines and to do research themselves on new and emerging technology that may impact the standards prior to the next meeting. The Committee members were asked to forward any related scientifically sound literature they found during their research onto the group for review.

The Chairperson stressed the importance of remaining objective in both the document reviews and in the meeting discussions. Discussions should focus on data, current relevant scientific literature, recommendations from the American College of Cardiology, The American Heart Association and the American Academy of Pediatrics (AAP) for Pediatric Cardiovascular Centers. Additionally, the group was reminded of the intent of the CON process in Michigan to assure adequate access, provide assurances of quality of service and to minimize cost. At the first meeting, the Committee discussed and voted to not add to the charges.

The Chairperson recommended that during the fact finding meetings, motions on the charges should be held until there was a common understanding of the issues impacting the standards. It was requested that all motions be put in the computer by the staff and projected on the wall screen. The individual who made the motion was required to confirm the wording of the motion prior to any further discussion or action.

Issues Addressed

Based on the review, committee members identified the following issues:

- Minimal availability of current data from primary percutaneous coronary intervention (PCI) cardiac catheterization programs performing primary PCI without on-site open heart surgery programs. Outcome data was obtained from CMS website.
- Current quality of reported physician volume data
- Need for reporting of physician volumes
- Intra-vascular (peripheral, non-cardiac) procedures performed in the cardiac catheterization laboratory and the multi-purpose rooms
- Current definitions of diagnostic and therapeutic procedures in the standards

- Methodology for computing cardiac catheterization procedures, equivalents, and weights
- Status of mobile cardiac catheterization network in the future
- Public reporting of morbidity/mortality rates

Discussion

A nominal grouping form was developed and distributed to the members to gather their recommendations, pros/cons of recommendations, and reference material to support the recommendations for each of the charges. It facilitated an understanding of the areas where there was general agreement as well as areas which had significant disparity. The feedback working document assisted the Committee with prioritization of the recommendations for discussion.

An analysis of the nominal grouping working document recommendations revealed that a majority of the Committee members agreed on issues that dealt with a facility's mandatory participation in the registry, minimum institutional volume requirement, modification of the procedure types, procedure equivalents and weights, and adequate access to cardiac cath services, but they disagreed on the minimum requirement of physician volumes for adult diagnostic procedures.

At the request of the Committee, a survey was conducted of other CON states. It resulted in obtaining responses from ten (10) states: Connecticut, Missouri, Nebraska, New Jersey, Ohio, Oregon, Rhode Island, Tennessee, Vermont, and West Virginia.

Charge 1:

Concerns regarding the quality outcome information of cardiac cath programs performing primary PCI without on-site open heart surgery programs were examined. Literature review included: Driving Times and Distances to Hospitals with Percutaneous Coronary Intervention in the United States published in Circulation (2006). Location of current programs and lack of access complaints was evaluated. Demographic information, including maps, was reviewed. Following discussion, the Committee members agreed that changes to the current standards for programs performing PCI without Open Heart programs should not be changed.

The Committee members agreed that participation in registries will consistently reduce the complications, help share advances in technology, allow benchmarking against other programs, and will result in quality improvement. Mandatory participation in a common registry will also set the foundation for public reporting should this be required in the future.

Presentations were made by BMC2 and ACC-NCDR representatives about their data registries. It was reported by BMC2 representatives that as of July 2007 all Therapeutic cardiac cath programs in Michigan are voluntarily participating in their registry. It was noted that they are providing the programs with some financial incentives to offset most of the cost of the data collection. The BMC2 registry does not contain information on Diagnostic procedures and covers only the State of Michigan. Representatives of ACC-NCDR reported that their registry is already in use at many Michigan facilities, allowing local and national

comparisons for both Diagnostic and Therapeutic catheterizations. Currently, all facilities in the United States that bill Medicare for implantation of Automated Implantable Cardiac Defibrillators (AICD), are required to participate in the ACC registry. It was noted that there are additional costs associated with participation in the ACC-NCDR registry that are not offset.

The committee members decided to recommend participation in ACC-NCDR as specified in charge 1, considering all the factors involved. They also strongly recommended that BMC2 registry and ACC-NCDR establish standard definitions within common data forms to provide the hospitals with the benefits of both registries and mitigate the administrative burden for data collection. By instituting this requirement, the committee was cognizant of cost burdens to hospitals; however, the outcomes of quality measures outweigh such burdens.

Charge 2:

Recommendations were made to keep the institutional volumes for adult diagnostic and therapeutic procedures, laboratories, and physician volumes for adult therapeutic procedures at current levels. The committee decided to deliberate further on physician volumes for adult diagnostic procedures and pediatric diagnostic and therapeutic procedures.

With regard to physician volume requirements for adult diagnostic procedures, there was discussion on whether there is a correlation between volumes and outcomes for diagnostic procedures. There was also discussion on how participation in the registry improves the quality of the programs. The committee reviewed ACC/AHA Guidelines, Journal of American Medical Association's article dated March 7, 2007 on "Opening of Specialty Cardiac Hospitals and Use of Coronary Revascularization in Medicare Beneficiaries" and Center for Medical Services document related to "Physician Quality Reporting Initiative," and finally decided to recommend to the Commission to eliminate the minimum physician volume requirements for adult diagnostic procedures.

The lack of a pediatric cardiologist on the committee resulted in the committee deciding to develop and send a survey form to seven of the top pediatric cardiologists in the state. The survey resulted in obtaining responses from two pediatric cardiologists, one from the U.P. and another one from the western part of the state.

Based on the recommendations from pediatric cardiologists and other experts on the committee, they decided to recommend to the Commission to keep the physician volumes for diagnostic and therapeutic pediatric procedures at current levels; and require facilities proposing to initiate a pediatric cardiac cath service to institute the following guidelines extracted from The American Academy of Pediatrics (AAP) for Pediatric Cardiovascular Centers (March 2002):

- A board certified cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory
- Standardized equipment as outlined in AAP Guidelines Publication

- On-Site ICU as outlined in AAP Guidelines Publication
- On-Site Pediatric Open Heart Surgery.

There is a recommendation that the designations of rural or urban pediatric cardiac catheterization facilities were removed from the standards and the volume requirements standardized. The Committee further made the recommendation that institution volumes shall be a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations to be performed annually. This recommendation will not affect the current programs. It was felt that the existing three programs met the needs for the State of Michigan and that there was not an access demand for additional programs.

Charge 3:

The experts on the Committee reviewed the past hospital records related to cardiac catheterization services. It was determined that new and emerging technology required the addition of procedure codes and weights. Existing procedures and weights in the standards needed to be modified in the current technology and practice. Committee members agreed with the experts' recommendations on procedures and weights. There was discussion regarding cardiac permanent pacemakers and ICD device implantations. The Committee is also recommending that cardiac permanent pacemakers/and ICD device implantations can be performed in diagnostic cardiac catheterization laboratories in hospitals that do not provide therapeutic cardiac catheterization services.

Charge 4:

The committee members reviewed annual hospital survey data, the MDCH article on "Diseases of the Heart in Michigan," and the location of cardiac catheterization centers by health services areas. The staff searched to find any evidence of oral or written complaints related to access issues and none were found. The Committee is reporting to the Commission that they have discussed issues related to the demonstrated need and compliance with regards to geographic locations, volume, and types of procedures, as specified in charge 4 and recommend that no specific action is required by the Commission at this time.

Charge 5:

There were no additional priority issues reported to the commission at the December 12, 2006 meeting that were not already included in the charge.

Conclusion

Final Recommendations

Recommendations addressing the four (4) charges:

Charge 1

- Facilities providing cardiac catheterization services in Michigan be required to participate in the American College of Cardiology National Cardiovascular Data Registry's CathPCI Registry (ACC-NDCR).

They also recommended that BMC2 registry and ACC-NCDR establish standard definitions within common data forms to provide the hospitals with the benefits of both registries. By instituting this requirement, the committee is cognizant of cost burdens to hospitals; however, the outcomes of quality measures outweigh such burdens.

The Committee was notified by e-mail that the two databases are currently working collaboratively on definitions, documents and plan on merging. The possibility of this happening had been discussed in the previous two years with little movement, however, given the discussions at the CCSAC meeting, it was evident the time to take action had arrived. The merging of these two excellent programs will reduce the administrative burden of data abstraction. It was recognized that this action will improve the quality of data reported, decrease administrative costs and improve care delivery to patients nationally. The two groups are to be commended on taking action to expedite this merger.

Charge 2

- Maintain the current institutional volume requirements for adult diagnostic and therapeutic cardiac catheterization services.
- Physician volume requirements for adult diagnostic cardiac catheterization services be eliminated.
- Physician volume requirements for pediatric diagnostic cardiac catheterization services remain at the current levels.
- Physician volume requirements for adult and pediatric therapeutic cardiac catheterization services remain at the current levels.
- Institutional volume shall be a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations to be performed annually.

Charge 3

- Proposed modifications in computing cardiac catheterization equivalents, procedures, and weights as follows:

	PROCEDURE EQUIVALENT	
PROCEDURE TYPE	**ADULT**	**PEDIATRIC**
DIAGNOSTIC CARDIAC CATHETERIZATION	1.0	3.0
THERAPEUTIC CARDIAC CATHETERIZATION	1.5	3.0

THERAPEUTIC,OTHER (PFO/ASD/VALVULOPLASTY,LVAD)	2.5	3.5
DIAGNOSTIC, Electro Physiology (EP)	2.0	3.5
THERAPEUTIC, EP – Permanent Pacemaker, ICD	2.5	5.0
THERAPEUTIC, EP – ABLATION NON-AF	3.0	5.0
THERAPEUTIC, EP – ABLATION AF OR VT	4.0	6.0
THERAPEUTIC, EP – CARDIOVERSION	1.0	1.0
DIAGNOSTIC, PERIPHERAL	1.0	2.0
THERAPEUTIC, PERIPHERAL-CAROTID,SUBCLAVIAN, RENAL, ILIAC, MESENTERIC	1.5	2.5
THERAPEUTIC, PERIPHERAL – Superficial Femoral Artery	2.5	2.5
THERAPEUTIC, PERIPHERAL – INFRAPOPLITEAL	3.0	3.0
THERAPEUTIC, PERIPHERAL – AORTA	4.0	4.0
OTHER PROCEDURES (IVC FILTER, TEMPORARY VENOUS PACEMAKER, IABP, OTHER RADIOLOGICAL PROCEDURES	1.0	2.0
MULTIPLE PROCEDURES WITHIN THE SAME SESSION (Diagnostic and/or Therapeutic)	The sum of procedure weights minus 0.5 for each procedure after the first procedure	The sum of procedure weights minus 0.5 for each procedure after the first procedure

Charge 4

- SAC reviewed data and discussed issues related to the demonstrated need and compliance with regards to geographic locations, volume, and types of procedures and recommend no specific action is required by the Commission at this time.

Additional Recommendations to CON Review Standards for Cardiac Cath Services

In addition, the committee made the following recommendations to the Commission:

- Cardiac permanent pacemaker/ICD device implantations can be performed in diagnostic cardiac cath laboratories in hospitals that do not provide therapeutic cardiac cath services.
- *Definition of Replace/Upgrade* to state "that involves a capital expenditure of $500,000 or more in any consecutive 24-month period which results in the applicant operating the same number of cardiac catheterization laboratories."

- Require facilities proposing to initiate a pediatric cardiac catheterization service to initiate the following guidelines extracted from The American Academy of Pediatrics (AAP) for Pediatric Cardiovascular Centers (March 2002):
  - A board certified cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory
  - Standardized equipment as outlined in AAP Guidelines Publication
  - On-Site ICU as outlined in AAP Guidelines Publication
  - On-Site Pediatric Open Heart Surgery
- *Definition of Intra-Vascular Catheterization* to state that: "intra-vascular catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into an artery in a patient. Subsequently, the free end of the catheter is manipulated by a physician to travel along the course of a non-coronary artery. X-rays and an electronic image intensifier are used as aids in placing the catheter tip into the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the artery. Intra-vascular catheterization shall not include "float catheters"or "hemodynamic monitoring catheters"which are performed, and/or are used at the bedside for the purposes of monitoring or administering hemodynamic medication."

Committee Members

Name	Contact Type
Robert Alpert	Consumer
Herbert D. Aronow, MD	Expert
Eric R. Bates, MD	Ex-Officio
Brooks R. Bock, MD	Expert
Simon R. Dixon, MD	Expert
Carol L. Joseph, RN - Chairperson	Expert
Barry K. Lewis, DO	Expert
Karen S. MacLachlan, RN	Expert
Sandy L. Reoma	Payer
Robert F. Stanton,	Provider
Gwen Thompson	Purchaser
Lois Van Donselaar, RN	Expert
Ronald L. Vanderlaan, MD	Expert
Bridget M. White – Vice Chairperson	Expert

Although the CCSAC membership is a matter of record, the members listed above were fully engaged in all aspects of the process. Without their steadfast and continued participation, the assigned task would have taken considerably longer.

The Chairperson would like to recognize the excellent support of Lakshmi Amarnath and the staff at MDCH. Their administrative support and expertise helped to create smooth functioning of the Committee meetings.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve cardiac catheterization services.

(2) Cardiac catheterization services are covered clinical services for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, **11** and ~~13~~ 14 as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section**s** ~~11~~ 12 **and 13** in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 3(2), IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) ~~As used in~~FOR PURPOSES OF these standards:

(a) "Balloon atrial septostomy" means a procedure in which a balloon-tipped catheter is placed across the atrial septum and withdrawn to create an enlarged atrial opening.

(b) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

(c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, as applicable, performed on a patient during a single session in a cardiac catheterization laboratory ~~or a multi purpose special radiological room~~. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. Cardiac catheterization shall not include "float catheters" which are performed at the bedside or in settings outside the cardiac catheterization laboratory ~~or multi purpose special radiological room.~~

(d) "Cardiac catheterization service" means the provision of one or more of the following types of procedures in compliance with Part 222 of the Code: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic cardiac catheterizations.

(e) "Central service coordinator" means the organizational ~~unit~~ ENTITY that has operational responsibility for a mobile cardiac catheterization network. It shall be a legal entity authorized to do business in Michigan.

(f) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(g) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(h) "Department" means the Michigan Department of Community Health (MDCH).

(i) "Diagnostic cardiac catheterization service" means providing diagnostic-only cardiac catheterizations on an organized, regular basis, ~~either~~ in a ~~room dedicated to that service or in a multi purpose special radiological room.~~LABORATORY. The term includes, but is not limited to: the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). For purposes of these standards, the term also includes balloon atrial septostomy procedure in a hospital that provides pediatric diagnostic cardiac catheterization services. THIS TERM ALSO INCLUDES CARDIAC PERMANENT PACEMAKER/ICD DEVICE IMPLANTATIONS IN A HOSPITAL THAT DOES NOT PROVIDE THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

(j) "Electrophysiology study" means a study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization procedure. The term also includes the implantation of permanent pacemakers and defibrillators.

(k) "Expand a cardiac catheterization service" means either:

(i) an increase in the number of cardiac catheterization laboratories ~~or multi purpose special radiological rooms~~ at a hospital; or

(ii) expanding the types of cardiac catheterization procedures authorized to be performed including adult or pediatric, diagnostic or therapeutic, at a hospital that currently performs cardiac catheterization procedures. ~~For purposes of these standards, a hospital that provides pediatric diagnostic cardiac catheterizations shall not be required to seek CON approval for a pediatric therapeutic cardiac catheterization service in order to perform a balloon atrial septostomy procedure.~~

(l) "Hospital" means a health facility licensed under Part 215 of the Code.

(m) "Host facility" means a hospital at which a mobile cardiac catheterization network is authorized to provide cardiac catheterization services.

(n) "ICD-9-CM code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

(o) "Initiate a cardiac catheterization service" means to begin performing cardiac catheterization procedures at a hospital that does not perform cardiac catheterization procedures as of the date an application is submitted to the Department.

(p) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(s) "Mobile cardiac catheterization network" means the provision of adult diagnostic-only cardiac catheterization services by a central service coordinator and two or more host ~~facilities.~~HOSPITALS.

~~(t) "Multi purpose special radiological room" or "room" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing special procedures and cardiac catheterization procedures.~~

(~~u~~T) "On-site open heart surgery services" means a facility that does have a CON to perform open heart surgery services and does perform open heart surgery services in the existing ~~facility.~~HOSPITAL.

(~~v~~U) "Pediatric cardiac catheterization service" means the offering and provision of cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies which are offered and provided to infants and children ages 14 and below, and others with congenital heart disease as defined by the ICD-9-CM codes of 426.7, 427.0, and 745.0 through 747.99.

(~~w~~V) "Primary percutaneous coronary intervention (PCI)" means ~~for the purposes of these standards~~ a PCI performed within 120 minutes for emergency acute myocardial infarction (AMI) patients seen in the emergency room (ER) with confirmed ST elevation or new left bundle branch block.

(~~x~~W) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory ~~or a multi purpose special radiological room~~ based on the type of procedures being performed.

~~(i) The following procedure equivalents shall be used in calculating and evaluating utilization of a cardiac catheterization laboratory or a multi purpose special radiological room:~~

~~Procedure Type~~	~~Procedure Equivalent~~ ~~Adult~~	~~Pediatric~~
~~Diagnostic cardiac catheterization~~	~~1.0~~	~~3.0~~
~~Therapeutic cardiac catheterization~~	~~1.5~~	~~3.0~~
~~Diagnostic electrophysiology study~~	~~3.0~~	~~4.0~~
~~Therapeutic electrophysiology study (including ablations)~~	~~4.0~~	~~6.0~~
~~Special procedure (non-cardiac)~~	~~1.0~~	~~1.0~~
~~Special procedure (cardiac, non-cath)~~	~~1.0~~	~~1.0~~
~~Diagnostic cardiac catheterization followed by a therapeutic cardiac catheterization in the same session~~	~~2.0~~	~~4.5~~
~~Multiple therapeutic procedures performed in the same session~~	~~2.0~~	~~4.5~~

~~(ii) For purposes of evaluating whether an applicant meets applicable volume requirements set forth in these standards, the applicable procedure equivalents for a "diagnostic cardiac catheterization followed by a therapeutic cardiac catheterization in the same session" shall be allocated entirely to the category of therapeutic cardiac catheterization.~~

~~(iii) For purposes of evaluating whether an applicant meets applicable volume requirements set forth in these standards, a balloon atrial septostomy procedure shall be considered a therapeutic cardiac catheterization, except for a hospital and a physician that performs this procedure as part of a diagnostic-only pediatric cardiac catheterization service, in which case the procedure shall be considered a pediatric diagnostic cardiac catheterization procedure.~~

(~~y~~X) "Replace/upgrade" means anY ~~an~~ equipment change THAT INVOLVES A CAPITAL EXPENDITURE OF $500,000 OR MORE IN ANY CONSECUTIVE 24-MONTH PERIOD ~~proposed by an applicant~~ which results in ~~that~~ THE applicant operating the same number of cardiac catheterization laboratories ~~or multi purpose special radiological rooms~~ before and after project completion.

(~~z~~Y) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

~~(aa) "Special procedure" means any angiographic or other invasive radiologic study other than a diagnostic or therapeutic cardiac catheterization or electrophysiology study performed during a single session in a cardiac catheterization laboratory or a multi purpose special radiological room.~~

~~(bb) "Therapeutic cardiac catheterization procedure" means a cardiac catheterization procedure used to treat and resolve anatomical and/or physiological problems in the heart. The term includes, but is not limited to: percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.~~

(~~cc~~Z) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis~~, either~~ in a laboratory TO TREAT AND RESOLVE ANATOMICAL AND/OR PHYSIOLOGICAL PROBLEMS IN THE HEART. THE TERM INCLUDES, BUT IS NOT LIMITED TO: PERCUTANEOUS CORONARY INTERVENTION (PCI), PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), ATHERECTOMY, STENT, LASER, CARDIAC VALVULOPLASTY, BALLOON ATRIAL SEPTOSTOMY, OR CATHETER ABLATION AND CARDIAC PERMANENT PACEMAKER/ICD DEVICE IMPLANTATIONS. THE TERM DOES NOT INCLUDE THE INTRA CORONARY ADMINISTRATION OF DRUGS WHERE THAT IS THE ONLY THERAPEUTIC INTERVENTION.~~dedicated to that service or in a multi purpose special radiological room.~~

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements for approval -- all applicants

Sec. 3. (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory ~~or multi purpose special radiological room~~ located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

~~(2) An application involving the provision of mobile cardiac catheterization services shall demonstrate that cardiac catheterization procedures will be performed within a hospital. The Department shall consider procedures performed in a mobile cardiac catheterization unit as within a hospital, if the mobile unit is or will be physically adjoined to the hospital by means of a connector such that patients will not be transported outside the hospital in order to receive cardiac catheterization services.~~

(~~3~~2) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. AN APPLICANT THAT IS INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED. ~~If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.~~

Section 4. Requirements for approval -- applicants ~~for~~ PROPOSING TO INITIATE an adult diagnostic cardiac catheterization service

Sec. 4. (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall project a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization will be performed in the second 12 months of operation after initiation of the adult diagnostic cardiac catheterization service, and annually thereafter.

(2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new single laboratory ~~or room~~ shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:

(a) For a hospital located in a rural or micropolitan statistical area county, a minimum of 500 procedure equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac catheterization required under subsection (1).

(b) For a hospital located in a metropolitan statistical area county, a minimum of 750 procedure equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac catheterization required under subsection (1).

(3) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in 2 or more laboratories ~~or rooms~~ shall project that a minimum of 1,000 procedure equivalents per laboratory~~/room~~ will be performed in the second 12 months of operation after initiation of the service, and annually thereafter. The projected volume shall include the procedure equivalents required by subsection (1).

~~(4) If the adult diagnostic cardiac catheterizations are to be performed in an additional laboratory or room added as part of an expansion of an existing cardiac catheterization service, an applicant shall also meet the requirements set forth in Section 7, as applicable.~~

Section 5. Requirements for approval -- applicants ~~for~~ PROPOSING TO INITIATE an adult diagnostic cardiac catheterization service with provision to perform primary PCI for patients experiencing AMI (ST elevation or new left bundle branch block) without on-site open heart surgery services

Sec. 5. (1) An applicant proposing to INITIATE ~~perform~~ primary PCI SERVICE without on-site open heart surgery services shall SUBMIT DOCUMENTATION demonstratING all of the following:

(a) The applicant's adult diagnostic cardiac catheterization service performed a minimum of 400 diagnostic procedures (excluding diagnostic electrophysiology studies and right heart catheterizations) during the most recent 12 months preceding the date the application was submitted to the Department. Mobile cardiac catheterization laboratories are not eligible to apply under Section 5.

(b) The interventional cardiologists (at least two) to perform the primary PCI are experienced interventionalists who have each performed at least 75 interventions annually as the primary operator at an open heart surgery facility during the most recent 24 months preceding the date the application was submitted to the Department, and annually thereafter.

(c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an open heart surgery facility; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency should be documented annually.

(d) The catheterization laboratory is well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.

(e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency should be documented annually.

(f) A written agreement with an open heart surgery facility that includes:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform primary PCI;

(ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI to ensure familiarity with interventional equipment; and competency should be documented annually;

(iii) Provision for ongoing cross training for Emergency Department, Catheterization Laboratory and Critical Care Unit staff to ensure experience in handling the high acuity status of primary PCI patient candidates and competency should be documented annually;

(iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI cases;

(v) Development and ongoing review of patient selection criteria for primary PCI patients and implementation of those criteria;

(vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care;

(vii) Written protocols, signed by the applicant and the open heart surgery facility, must be in place, with provisions for the implementation for immediate and efficient transfer (within 1 hour from cardiac catheterization laboratory to evaluation on site in the open heart surgical facility) of patients requiring

surgical evaluation and/or intervention 365 days a year, the protocols shall be reviewed/tested on a regular (quarterly) basis; and

(viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

(g) A written protocol must be established and maintained for case selection for the performance of primary PCI that is consistent with current practice guidelines set forth by the American College of Cardiology and the American Heart Association.

(h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the Emergency Department to the Catheterization Laboratory must be developed and maintained so that door-to-balloon targets are met.

(i) Because primary PCI must be available to emergency patients 24 hours per day, 365 days a year, at least two physicians credentialed to perform primary PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to primary PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the American College of Cardiology and American Heart Association.

(2) An applicant shall project a minimum of 48 primary PCI procedures will be performed in the second 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume shall be projected by documenting, as outlined in Section 13, and certifying that the applicant treated or transferred enough ST segment elevation AMI cases during the most recent 12 months preceding the date the application was submitted to the Department to maintain 48 primary PCI cases annually. Factors that may be considered in projecting primary PCI volume are the number of thrombolytic eligible patients per year seen in the Emergency Department (as documented through hospital pharmacy records showing the number of doses of thrombolytic therapy ordered for AMI in the Emergency Department) and/or documentation of emergency transfers to an open heart surgery facility for primary PCI.

Section 6. Requirements for approval -- applicants ~~for~~ PROPOSING TO INITIATE a pediatric ~~diagnostic~~ cardiac catheterization service

Sec. 6. (1) An applicant proposing to initiate a pediatric ~~diagnostic~~ cardiac catheterization service at a hospital that will perform ~~only pediatric diagnostic~~ cardiac catheterization procedures IS REQUIRED TO HAVE ~~shall demonstrate~~ each of the following~~, as applicable:~~AS OUTLINED IN THE AMERICAN ACADEMY OF PEDIATRICS (AAP), GUIDELINES FOR PEDIATRIC CARDIOVASCULAR CENTERS (MARCH 2002):

(A) A BOARD CERTIFIED PEDIATRIC CARDIOLOGIST WITH TRAINING IN PEDIATRIC CATHETERIZATION PROCEDURES TO DIRECT THE PEDIATRIC CATHETERIZATION LABORATORY;

(B) STANDARDIZED EQUIPMENT AS OUTLINED IN AAP GUIDELINES PUBLICATION;

(C) ON-SITE ICU AS OUTLINED IN AAP GUIDELINES PUBLICATION; AND

(D) ON-SITE PEDIATRIC OPEN HEART SURGERY.

~~(a) A minimum of 450 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations will be performed in the second 12 months of operation after initiation of the pediatric diagnostic cardiac catheterization service, and annually thereafter.~~

~~(b) If pediatric diagnostic cardiac catheterizations are to be performed in a new single laboratory or room, an applicant shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:~~

~~(i) For a hospital located in a rural county, a minimum of 500 procedure equivalents which shall include the 450 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations as required by subsection (a).~~

~~(ii) For a hospital located in a non-rural county, a minimum of 750 procedure equivalents which shall include the 450 procedure equivalents in the category of pediatric diagnostic cardiac catheterizations as required by subsection (a).~~

(2) An applicant proposing to initiate a pediatric ~~diagnostic~~ cardiac catheterization service at a hospital that currently performs ~~adult diagnostic~~ cardiac catheterization procedures shall ~~demonstrate~~ PROJECT ~~each of the following, as applicable:~~THAT ~~(a)~~ a minimum of ~~150~~ 600 procedure equivalents in the category of pediatric ~~diagnostic~~ cardiac catheterizations will be performed in the second 12 months of operation after initiation of the pediatric ~~diagnostic~~ cardiac catheterization service, and annually thereafter.

~~(b) A minimum of 1,000 procedure equivalents in the category of adult diagnostic cardiac catheterization was performed in the most recent 12-month period preceding the date the application was submitted to the Department.~~

~~(c) If an application involves an additional laboratory or room, an applicant shall also demonstrate the proposed application meets the requirements of Section 7, as applicable.~~

~~**Section 7. Requirements for approval -- applicants proposing to add a cardiac catheterization laboratory or multi purpose special radiological room**~~

~~Sec. 7. An applicant proposing to add a laboratory or room, whether a dedicated cardiac catheterization laboratory or a multi purpose special radiological room, to an existing cardiac catheterization service shall demonstrate both of the following:~~

~~(a) An average of 1,500 procedure equivalents per room per year was performed in each existing cardiac catheterization laboratory and multi purpose special radiological room in the hospital during the most recent 12-month period preceding the date the application was submitted to the Department.~~

~~(b) An average of 1,000 procedure equivalents will be performed in each cardiac catheterization laboratory and multi purpose special radiological room (both existing and proposed) in the second 12 months of operation after initiating operation of the additional room, and annually thereafter.~~

Section ~~8~~7.~~.~~ Requirements for approval -- applicants ~~for a~~PROPOSING TO INITIATE AN ADULT therapeutic cardiac catheterization service

Sec. ~~8~~7.~~.~~ (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall demonstrate both of the following:

(a) An applicant provides or has CON approval to provide an adult ~~or pediatric, as applicable,~~ diagnostic cardiac catheterization service.

(b) An applicant provides or has CON approval to provide an adult ~~or pediatric, as applicable,~~ open heart surgery service ~~performing emergent, urgent, and elective open heart surgery~~ within the hospital in which the therapeutic cardiac catheterizations are to be performed.

(c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.

(2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:

~~(a) A minimum of 150 procedure equivalents in the category of pediatric therapeutic cardiac catheterizations.~~

(~~b~~A) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations.

~~(3) If the therapeutic cardiac catheterization procedures are proposed to be performed in a new or additional laboratory or room added as part of the initiation or an expansion of cardiac catheterization service, an applicant shall also meet the requirements set forth in Section 4 or 7, as applicable.~~

~~**Section 8. Requirements for approval -- applicants for a therapeutic cardiac catheterization service**~~

~~Sec. 8. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall demonstrate both of the following:~~

~~(a) An applicant provides or has CON approval to provide an adult or pediatric, as applicable, diagnostic cardiac catheterization service.~~

~~(b) An applicant provides or has CON approval to provide an adult or pediatric, as applicable, open heart surgery service performing emergent, urgent, and elective open heart surgery within the hospital in which the therapeutic cardiac catheterizations are to be performed.~~

~~(c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.~~

~~(2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:~~

~~(a) A minimum of 150 procedure equivalents in the category of pediatric therapeutic cardiac catheterizations.~~

~~(b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations.~~

~~(3) If the therapeutic cardiac catheterization procedures are proposed to be performed in a new or additional laboratory or room added as part of the initiation or an expansion of cardiac catheterization service, an applicant shall also meet the requirements set forth in Section 4 or 7, as applicable.~~

Section ~~98.~~ Requirements for approval -- applicants ~~for~~ PROPOSING TO replace~~ment~~/upgradE~~upgrading of~~ cardiac catheterization laboratories. ~~or multi purpose special radiological rooms~~

Sec. ~~98.~~ (1) ~~If an~~ An applicant, other than a hospital that provides only pediatric cardiac catheterization services, ~~is~~ proposing to replace/upgrade ~~an existing cardiac catheterization~~ITS ONLY ~~catheterization~~ laboratory, ~~or multi purpose special radiological room and the laboratory or room is the only laboratory or room at the hospital in which cardiac catheterization procedures are performed, an applicant~~ shall demonstrate that it meets each of the following, as applicable:

(a) For a hospital located in a rural county:

(i) A minimum of 500 procedures equivalents were performed in the applicant's cardiac catheterization LABORATORY/~~multi purpose special radiological room~~ during the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(ii) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory~~/multi purpose special radiological room~~ in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(b) For a hospital located in a non-rural county:

(i) A minimum of 750 procedure equivalents was performed in the applicant's cardiac catheterization laboratory~~/multi purpose special radiological room~~ during the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(ii) A minimum of 750 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory~~/multi purpose special radiological room~~ in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(2) If an applicant is a hospital that provides only pediatric cardiac catheterization services proposes to replace/upgrade an existing cardiac catheterization laboratory ~~or multi purpose special radiological room and the room is the only room at the hospital in which cardiac catheterization procedures are performed,~~ an applicant shall demonstrate that it meets each of the following:

(a) A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization laboratory~~/multi purpose special radiological room~~ in the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(b) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory~~/multi purpose special radiological room~~ in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(3) ~~If an~~ An applicant ~~is proposing to replace/upgrade an existing cardiac catheterization laboratory or multi purpose special radiological room and there are~~WITH ~~are~~ 2 or more ~~existing rooms at the hospital in which cardiac catheterization procedures are performed,~~LABORATORIES PROPOSING TO REPLACE/UPGRADE ANY OF ITS LABORATORIES ~~the applicant~~ shall demonstrate that it meets each of the following, AS APPLICABLE:

(a) An average of 1,000 procedure equivalents per room was performed in each existing cardiac catheterization laboratory ~~and multi purpose special radiological room~~ in the hospital during the most recent 12 months of ~~normal~~ operation preceding the date the application was submitted to the Department, and

(b) A minimum of 1,000 procedure equivalents will be performed in each cardiac catheterization laboratory ~~and multi purpose special radiological room~~ in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(4) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be replaced is fully depreciated according to generally accepted accounting principles, or can clearly demonstrate that the existing equipment poses a threat to the safety of the public, or offers significant technological improvements which enhance quality of care, increases efficiency, and/or reduces operating costs.

(5) If an application involves the replacement/upgrade of equipment used by a mobile cardiac catheterization network, an applicant shall demonstrate both of the following:

(a) At least 500 procedure equivalents were performed in the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

(b) A minimum of 500 procedure equivalents will be performed in the first 12 months of operation after installation of the new equipment, and annually thereafter.

(c) In evaluating compliance with subsections (a) and (b), the Department shall consider the combined utilization for all approved host facilities.

(6) In demonstrating compliance with the minimum volume requirements set forth in each applicable subsection of this section, an applicant shall demonstrate that the minimum volume requirement applicable to the specific type of cardiac catheterization procedures offered by an applicant (adult, pediatric, diagnostic or therapeutic) as set forth in Section 4(1), ~~6(1)(a),~~ 6(2)(~~a)~~ or ~~8~~7(2)(~~a~~A)~~ or (b)~~, as applicable, have also been met.

SECTION 9. REQUIREMENTS FOR APPROVAL -- APPLICANTS PROPOSING TO EXPAND A CARDIAC CATHETERIZATION SERVICE BY ADDING A LABORATORY

SEC. 9 AN APPLICANT PROPOSING TO ADD A LABORATORY TO AN EXISTING CARDIAC CATHETERIZATION SERVICE SHALL DEMONSTRATE BOTH OF THE FOLLOWING:

(A) AN AVERAGE OF 1,500 PROCEDURE EQUIVALENTS PER ROOM PER YEAR WAS PERFORMED IN EACH EXISTING CARDIAC CATHETERIZATION LABORATORY IN THE HOSPITAL DURING THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

(B) AN AVERAGE OF 1,000 PROCEDURE EQUIVALENTS WILL BE PERFORMED IN EACH CARDIAC CATHETERIZATION LABORATORY (BOTH EXISTING AND PROPOSED) IN THE SECOND 12 MONTHS OF OPERATION AFTER INITIATING OPERATION OF THE ADDITIONAL ROOM, AND ANNUALLY THERE AFTER.

Section 10. Requirements for approval -- applicants for a mobile cardiac catheterization network

Sec. 10. An application involving a mobile cardiac catheterization network shall demonstrate that it meets each of the following, as applicable:

(1) An application will not result in an increase in the number of mobile cardiac catheterization networks with valid CON approval as of the effective date of these standards.

(2) An application will not result in an increase in the number of host facilities being served by a mobile cardiac catheterization network from the number of host facilities authorized to be served by that same network as of the effective date of these standards.

(3) An application does not involve the initiation of a mobile cardiac catheterization network not authorized by a valid CON as of the effective date of these standards.

(4) AN APPLICATION INVOLVING THE PROVISION OF MOBILE CARDIAC CATHETERIZATION SERVICES SHALL DEMONSTRATE THAT CARDIAC CATHETERIZATION PROCEDURES WILL BE PERFORMED WITHIN A HOSPITAL. THE DEPARTMENT SHALL CONSIDER PROCEDURES PERFORMED IN A MOBILE CARDIAC CATHETERIZATION UNIT AS WITHIN A HOSPITAL, IF THE MOBILE UNIT IS OR WILL BE PHYSICALLY ADJOINED TO THE HOSPITAL BY MEANS OF A CONNECTOR SUCH THAT PATIENTS WILL NOT BE TRANSPORTED OUTSIDE THE HOSPITAL IN ORDER TO RECEIVE CARDIAC CATHETERIZATION SERVICES.

SECTION~~Section~~ 11. METHODOLOGY FOR COMPUTING CARDIAC CATHETERIZATION EQUIVALENTS – PROCEDURES AND WEIGHTS~~Project delivery requirements -- terms of approval for all applicants~~

SEC.~~Sec.~~11. (1) THE FOLLOWING PROCEDURE EQUIVALENTS SHALL BE USED IN CALCULATING AND EVALUATING UTILIZATION OF A CARDIAC CATHETERIZATION LABORATORY:

	PROCEDURE EQUIVALENT	
PROCEDURE TYPE	**ADULT**	**PEDIATRIC**
DIAGNOSTIC CARDIAC CATHETERIZATION	1.0	3.0
THERAPEUTIC CARDIAC CATHETERIZATION	1.5	3.0
THERAPEUTIC,OTHER (PFO/ASD/VALVULOPLASTY,LVAD)	2.5	3.5
DIAGNOSTIC, PERIPHERAL[1]	1.0	2.0
THERAPEUTIC, PERIPHERAL-CAROTID,SUBCLAVIAN, RENAL, ILIAC, MESENTERIC	1.5	2.5
THERAPEUTIC, PERIPHERAL – Superficial Femoral Artery	2.5	2.5
THERAPEUTIC, PERIPHERAL – INFRAPOPLITEAL	3.0	3.0
THERAPEUTIC, PERIPHERAL – AORTA	4.0	4.0

[1] Excludes selective common femoral angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible closure device.

	PROCEDURE EQUIVALENT	
PROCEDURE TYPE	**ADULT**	**PEDIATRIC**
DIAGNOSTIC, Electro Physiology (EP)	2.0	3.5
THERAPEUTIC, EP – Permanent Pacemaker, ICD	2.5	5.0
THERAPEUTIC, EP – ABLATION NON-AF	3.0	5.0
THERAPEUTIC, EP – ABLATION AF OR VT	4.0	6.0
THERAPEUTIC, EP – CARDIOVERSION	1.0	1.0
OTHER PROCEDURES (IVC FILTER, TEMPORARY VENOUS PACEMAKER, IABP, OTHER RADIOLOGICAL PROCEDURES	1.0	2.0
MULTIPLE PROCEDURES WITHIN THE SAME SESSION (Diagnostic and/or Therapeutic)	The sum of procedure weights minus 0.5 for each procedure after the first procedure	The sum of procedure weights minus 0.5 for each procedure after the first procedure

(2) FOR PURPOSES OF EVALUATING WHETHER AN APPLICANT MEETS APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THESE STANDARDS, CARDIAC CATHETERIZATION PROCEDURES PER LABORATORY MUST BE MET EXCLUSIVE OF THE INTRA-VASCULAR CATHETERIZATION PROCEDURES WHEN CONSIDERING EXPANSION OR REPLACE/UPGRADE. THE PERIPHERAL NON-CARDIAC PROCEDURES SHALL COUNT TOWARD THE TOTAL VOLUME REQUIREMENTS FOR PROCEDURES BUT THE MINIMUM VOLUMES REMAIN THE SAME FOR INITIATION OF CARDIAC CATHETERIZATION SERVICES.

(A) INTRA-VASCULAR CATHETERIZATION IS A MEDICAL DIAGNOSTIC OR THERAPEUTIC PROCEDURE DURING WHICH A CATHETER IS INSERTED INTO AN ARTERY IN A PATIENT. SUBSEQUENTLY, THE FREE END OF THE CATHETER IS MANIPULATED BY A PHYSICIAN TO TRAVEL ALONG THE COURSE OF A NON-CORONARY ARTERY. X-RAYS AND AN ELECTRONIC IMAGE INTENSIFIER ARE USED AS AIDS IN PLACING THE CATHETER TIP INTO THE DESIRED POSITION. WHEN THE CATHETER IS IN PLACE, THE PHYSICIAN IS ABLE TO PERFORM VARIOUS DIAGNOSTIC STUDIES AND/OR THERAPEUTIC PROCEDURES IN THE ARTERY. INTRA-VASCULAR CATHETERIZATION SHALL NOT INCLUDE "FLOAT CATHETERS" OR "HEMODYNAMIC MONITORING CATHETERS" WHICH ARE PERFORMED, AND/OR ARE USED AT THE BEDSIDE FOR THE PURPOSES OF MONITORING OR ADMINISTERING HEMODYNAMIC MEDICATION.

Section ~~11~~12. Project delivery requirements -- terms of approval for all applicants

Sec. ~~11~~12. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following quality assurance standards:

(i) The approved services ~~and/or laboratories/rooms~~ shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The approved services shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

(iii) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including: complication rates (including emergency surgical procedures); morbidity and mortality data; success rates and the number of procedures performed.

~~(iv) Each physician credentialed by a hospital to perform adult diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 100 adult diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means adult diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of adult diagnostic cardiac catheterization procedures performed by each physician credentialed to perform adult diagnostic cardiac catheterization procedures.~~

(~~v~~IV) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac catheterization procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of adult therapeutic cardiac catheterization procedures performed by each physician credentialed to perform adult therapeutic cardiac catheterization procedures.

(~~vi~~V)~~)~~ Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of pediatric diagnostic cardiac catheterization procedures performed by each physician credentialed to perform pediatric diagnostic cardiac catheterization procedures.

(~~vii~~VI) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac catheterizations per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of pediatric therapeutic cardiac catheterization procedures performed by each physician credentialed to perform pediatric therapeutic cardiac catheterization procedures.

(~~viii~~VII) For purposes of evaluating subdivisions ~~(iv),~~ (v), OR (vi~~), or (vii),~~ a diagnostic cardiac catheterization followed by a therapeutic cardiac catheterization (including electrophysiology studies) in the same session shall be considered both 1 diagnostic procedure and 1 therapeutic procedure. Two physicians, one credentialed to perform diagnostic cardiac catheterizations and one credentialed to perform therapeutic cardiac catheterizations, each may be considered to have performed either 1 diagnostic or 1 therapeutic catheterization if both were involved in performing a diagnostic cardiac catheterization procedure followed by a therapeutic procedure in the same session.

(~~ix~~VIII) An applicant proposing to offer an adult diagnostic cardiac catheterization service shall have a minimum of two (2) appropriately trained physicians on its active hospital staff. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if the staff physicians:

(A) are trained consistent with the recommendations of the American College of Cardiology;

(B) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and

(C) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months.

However, the applicant may submit and the Department may accept other evidence that the staff physicians performing adult diagnostic cardiac catheterizations are appropriately trained.

(~~x~~IX) An applicant proposing to offer an adult therapeutic cardiac catheterization service shall have a minimum of two (2) appropriately trained physicians on its active hospital staff. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if the staff physicians:

(A) are trained consistent with the recommendations of the American College of Cardiology;

(B) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and

(C) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

However, the applicant may submit and the Department may accept other evidence that the staff physicians performing adult therapeutic cardiac catheterizations are appropriately trained.

(~~xi~~X) An applicant proposing to offer a pediatric cardiac catheterization service shall demonstrate an appropriately trained physician(s) shall be on the active hospital staff to perform diagnostic or therapeutic, as applicable, pediatric cardiac catheterizations. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training if the staff physician(s) is:

(A) board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;

(B) credentialed by the hospital to perform diagnostic or therapeutic, as applicable, pediatric cardiac catheterizations; and

(C) trained consistently with the recommendations of the American College of Cardiology.

However, the applicant may submit and the Department may accept other evidence that the staff physician(s) performing pediatric cardiac catheterizations is appropriately trained.

(~~xii~~XI) A cardiac catheterization service shall be directed by an appropriately trained physician. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of appropriate training and experience of the cardiac catheterization service director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations per year during each of the 5 preceding years. However, the applicant may submit and the Department may accept other evidence that the cardiac catheterization service director is appropriately trained.

(~~xiii~~XII) An approved cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

(~~xiv~~XIII) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(d) Compliance with the following terms of approval:

(i) Equipment that is replaced shall be removed from the cardiac catheterization service.

(ii) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) Not deny cardiac catheterization services to any individual based on ability to pay or source of payment;

(B) Provide cardiac catheterization services to all individuals based on the clinical indications of need for the service; and

(C) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources and other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site or unit as required by the Department, in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(IV) THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS REQUIRED BY THE

DEPARTMENT. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND MONITOR VOLUMES AND ASSURE QUALITY. AN APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY UPON INITIATION OF THE SERVICE AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(~~iv~~V) The applicant shall provide the Department with a notice stating the date on which the first approved service is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(~~v~~VI) The applicant shall accept referrals for cardiac catheterization services from all appropriately licensed health care practitioners.

(2) The agreements and assurances required by this section shall be in the form of a certification AGREED TO BY ~~authorized by the governing body of~~ the applicant OR ITS AUTHORIZED AGENT.

Section ~~12~~13~~.~~ Project delivery requirements – additional terms of approval for applicants approved under Section 5

Sec. ~~12~~ 13. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(b) Compliance with requirements of the standards set forth in Section 5(1).

(2) The applicant shall have performed a minimum of 48 primary PCI procedures at the facility in the preceding 12 months AND ANNUALLY THEREAFTER.

(3) The applicant shall participate in a data registry, administered by the Department or its designee. The Department or its designee shall require that the applicant submit data on all consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative analyses of case selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the required data in a format established by the Department or its designee. The applicant shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality.

Section ~~13~~14. Documentation of projections

Sec. ~~13~~14. An applicant required to project volumes of service under sections 4, 5, 6, and 7~~, 8, and 9~~ shall specify how the volume projections were developed. This specification of the projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section ~~14~~15. Effect on prior CON Review Standards; comparative reviews

Sec. 14. (1) These CON Review Standards supercede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on ~~June 10, 2003~~MARCH 9, 2004 and effective on ~~August 4, 2003~~JUNE 4, 2004.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

CON REVIEW STANDARDS
FORCARDIAC CATHETERIZATION SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MEMORANDUM – SUMMARY REPORT

Date: September 12, 2007

From: James K. Delaney, Chairman, OHS SAC

To: Norma Hagenow, Chairperson, Certificate of Need Commission
Edward Goldman, Vice-Chair, Certificate of Need Commission

RE: Open Heart Surgery Standard Advisory Committee

Dear Norma and Ed:

The Open Heart Surgery Services Standard Advisory Committee began meeting in January 2007 with the Charge to address the following issues, as approved by the Certificate of Need (CON) Commission on June 21, 2006:

1. Review and consider public reporting of risk adjusted outcomes.
2. Review and determine minimum institutional and physician volume requirements in the Certificate of Need Review Standards for Open Heart Surgery Services.
3. Review and consider mandating the participation in a quality/risk adjusted outcome/database.
4. Report to the Commission at the December 12, 2006 meeting about any additional priority issues not in the Charge.
5. How to demonstrate need and compliance looking at geographic locations, volume, length of commitment, and types of procedures.

The fourth point in the Charge was immediately dismissed because the Committee had not been seated by this deadline so, for purposes of discussion going forward, the remaining items will be referred to as items 1 – 4.

The twelve member Committee included experts in thoracic and cardiovascular surgery, consumers, health care purchasers, payers, and providers. The Committee's term commenced on January 17, 2007, with its first meeting, and expired on July 17, 2007. Seven meetings of the SAC were held during this period[1].

1. Review and consider public reporting of risk adjusted outcomes.

The Committee welcomed a presentation by Dr. Prager, Committee member, regarding the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) – BCBSM Quality Collaborative and the Measurement of Adult Cardiac Surgery Quality nationally.

[1] Meeting dates (2007): January 17, February 15, March 20, April 19, May 15, June 5 and July 11.

Through the Society, all surgeons and hospitals throughout the State report case and outcome data voluntarily and meet quarterly to discuss outcomes, emergent techniques, and self-police their profession. This program has become a model throughout the country as other states aspire to adopt such programs.

The Committee agreed that there are currently no indicators that prove in any way that public reporting improves quality and outcomes. The Committee feels strongly that collaborative partnerships with physicians (such as that with MSTCVS) can raise the bar, improving processes and quality. If there is any benefit to public reporting, we do not have the means or knowledge at this time to report accurately and responsibly. Given the fact that the MSTCVS already has a viable program for monitoring performance in place, the Committee felt strongly that no other mechanism was necessary or appropriate at this time, but that all programs should be mandated to participate in the STS database and the program's state-wide auditing. In summary, at this time the Committee does not recommend public reporting of risk-adjusted outcomes. While the Committee's recommendation may be an unpopular position, the Committee feels confident that the existent program well serves the existent need. That being said, the Department should be prepared for the initiation of a State-based program in the event that the BCBSM/MSTCVS partnership program loses its funding. In such a case, the State should partner with MSTCVS to monitor open heart programs and outcomes in the State.

2. Review and determine minimum institutional and physician volume requirements in the Certificate of Need Review Standards for Open Heart Surgery Services.

When the Committee first began to discuss this matter, the Department was kind enough to give a presentation on the methodology used to compute the number of open heart surgical cases. It was clear that the old methodology (from 1986) was dated and that the listing of 1CD-9-CM Codes would have to be reviewed and updated before we were able to consider volumes; we needed to have a sense for what effect any revisions to the methodology and coding could potentially have on volumes. As a result, a Sub-Committee was formed to evaluate current codes in use, their appropriateness, and possible additional codes. The Sub-Committee's analysis resulted in the following recommendations:

Delete the following codes from the Department's list:

- 37.68 (Insertion of percutaneous external heart assist device)
- 37.61 (Implant of pulsation balloon)

Add the following codes:

- Most of the 35 procedure codes (Operations on valves and septa of heart; these were previously counted under a single code, 39.61, for on-pump procedures)
- 37.74 (Insertion or replacement of epicardial lead [electrode] into epicardium)
- 37.77 (Removal of lead(s) [electrode] without replacement)
- 39.62 (Hypothermia (systemic) incidental to open heart surgery)
- 39.73 (Endovascular implantation of graft in thoracic aorta)

The Department ran test data from several hospitals to determine the effects of the revised coding and the Committee was satisfied that the volume result variance was insignificant. Discussion took place as to the existent diagnosis groupings and weights in the standards and the Sub-Committee reviewed the groupings to ensure that they are appropriate and complete. The following additional Major ICD-9-CM Code Groups were added to Group G (All Other Heart Conditions), as referred to in the methodology section of the standards for adult open heart surgical procedures:

- 164.1 (Malignant Neoplasm of Heart)
- 212.7 (Benign Neoplasm of Heart)
- 441.01 (Dissection of Thoracic aorta)
- 441.03 (Dissection of Thoracoabdominal aorta)
- 441.1 (Thoracic aneurysm, ruptured)
- 441.2 (Thoracic aneurysm without mention of rupture)
- 441.6 (Thoracoabdominal aneurysm, ruptured)
- 441.7 (Thoracoabdominal aneurysm, without mention of rupture)
- 785.51 (Cardiogenic Shock)
- 901.0 (Injury to blood vessels of Thoracic aorta)
- 996.02 (Mechanical Complication due to Heart Valve Prosthesis)
- 996.03 (Mechanical Complication due to Coronary Bypass Graft)

During the twenty-one years that the existent ICD-9-CM Codes and the weights have been in place, there have been dramatic changes in practice patterns and procedures. The Committee is confident in the revised procedure codes, but the Department will be recommending revisions to the weighting and methodology as additional analysis is necessary.

Discussion took place regarding how the standard of 300 adult open heart surgical procedures was determined and changed from 200, as in the past. The Committee agreed that the group wanted background on that change before going forward on a recommendation. After lengthy discussion including public comment, the Committee decided to recommend that the institutional standard of 300 adult open heart surgery cases, established in 1993, be maintained. While there is no conclusive evidence supporting the point-of-view, there appears to be significant anecdotal evidence that larger volume institutions tend to have better quality and risk-adjusted outcomes. (California's unregulated environment, where low volume institutions proliferate and outcomes are statistically less favorable, would support the Committee's recommendation.) In addition to the successful motion to maintain the institutional standard of 300 adult open heart surgery cases, some Committee members felt strongly that this report also include the statement: "There are no specific evidence-based numbers that there is agreement on in terms of what an adequate volume number is and that there are very high-quality low-volume programs, as well as lesser-quality high-volume programs; the literature suggests that even at 200 or 100, there are several quality programs. The SAC strongly supported outcomes evaluation based on the quality of the program as a much stronger indicator than any specific number."

In terms of the current institutional standard of 100 pediatric open heart surgical procedures, the Committee felt that since there were no pediatric cardiac surgeons represented, we were not in a position to make any recommendation. The Committee also agreed that the word "procedure" be replaced wherever it appeared in the standards with "cases" for count purposes, as any given case could possibly involve multiple procedures.

The Committee recommends that each physician credentialed by an applicant hospital to perform adult open heart surgery cases, as the attending physician, shall perform a minimum of 75 adult open heart surgery cases per year; this is a revision from 50 adult open heart cases per year. The relationship between physician volume and better outcomes is notable; reports indicate that as a group, high volume surgeons generally have lower patient mortality rates than those doing fewer procedures. In addition, the Blue Cross Blue Shield Association has a Blues Distinction Centers for Cardiac Care Program, which is equivalent to the Centers for Excellence model. Their requirement is a volume of 75 for the operator; this standard came about by an expert panel of cardiac surgeons who agreed that 75 is the threshold. They also have a standard indicating that the majority of procedures (75 percent) performed at the institution should be done by high volume surgeons.

A hospital proposing to initiate open heart surgery as a new service shall have a written consulting agreement with a hospital which has an existing active open heart surgery service. Currently a consulting hospital's open heart program must perform a minimum of 350 cases per year; the Committee recommends that consulting hospitals be required to perform a minimum of 400 cases per year for at least three consecutive years. The number 400 was not determined in any scientific manner; however the 350 number has been in place for many years and did not increase when the hospital standard for open heart volume increased from 200 to 300. There was general consensus that a consulting program should be a higher volume operator with greater expertise and skills to consult. While the number 400 is only a modest increase, there was a concern that raising the number more significantly could dramatically limit the number of viable programs that could qualify as consulting hospitals.

Finally, the Committee recommends that any new open heart surgery programs be required to undergo a quality review program at the end of the first three years of operation; the quality review program should be conducted by MDCH in conjunction with MSTCVS.

3. Review and consider mandating the participation in a quality/risk adjusted outcome/database.

The Committee feels strongly that all open heart programs should be required to participate in the STS database and the program's state-wide auditing. The Committee strongly supports outcomes evaluation based on the quality of the program as a much stronger indicator than any specific volume number. The literature suggests that there are high quality, lower volume programs, as well as lesser quality, high volume programs.

4. How to demonstrate need and compliance looking at geographic locations, volume, length of commitment, and types of procedures.

The Committee agreed to continue to require hospital(s) committing MIDB data to be located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

The Committee agreed that once MIDB data was committed to support a CON application for open heart surgery services, it should not be recommitted, and the wording in the current standards regarding the ability to recommit data after seven years should be eliminated. However, any incremental increase in MIDB data could be committed to support a CON application for open heart surgery services. Additionally, if the hospital(s) committing data have experienced growth in their own program, and wish to initiate an open heart surgery service, the hospital(s) may use all of their MIDB data to support their own CON application and meet initiation volume requirements. The Committee took this approach to be able to address significant demographic growth in a market.

In addition to the specific Charge matters, the Committee also further clarified the definitions of adult and pediatric open heart surgery in the Standards.

In conclusion, I applaud the Commission for selecting such a talented and conscientious panel for the OHS SAC. All of the Committee members performed very admirably during some very challenging discussions. The group clearly took our Charge and mission for the people of the State of Michigan very seriously. Thank you for the opportunity to serve the people of the State once again with such an outstanding group of professionals.

Best Regards,

Jim

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR OPEN HEART SURGERY SERVICES

(By the authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve open heart surgery services.

(2) Open heart surgery is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, ~~5~~, 6, 8, and 9, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 7 in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 5 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) FOR PURPOSES OF~~As used in~~ these standards:

(a) “Adult open heart surgery” means open heart surgery offered and provided to individuals age 15 and older AS DEFINED IN SUBSECTION (I).

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of open heart surgery.

(c)"Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Department" means the Michigan Department Of Community Health (MDCH).

(f) "ICD-9-CM code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

(g) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(h) "Michigan inpatient data base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(J) "OPEN HEART SURGICAL CASE" MEANS A SINGLE VISIT TO AN OPERATING ROOM DURING WHICH ONE OR MORE OPEN HEART SURGERY PROCEDURES ARE PERFORMED.

(Kj) "Open heart surgery service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An open heart surgery service performs open heart surgery procedures on an emergent, urgent and scheduled basis.

(Lk) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and children age 14 and YOUNGERbelow, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(Ml) "Planning area" means the groups of counties shown in Section 10.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for ALL APPLICANTS PROPOSING TO INITIATE OPEN HEART SURGERY SERVICESapproval -- all applicants

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new service shall BE OPERATING OR APPROVED TO OPERATE Ahave in place, or meet the CON review standards for initiation of diagnostic and therapeutic adult or pediatric cardiac catheterization services, respectively.

(2) A hospital proposing to initiate open heart surgery as a new service shall have a written consulting agreement with a hospital which has an existing active open heart surgery service performing a minimum of 400350 open heart surgical CASESprocedures per year FOR 3 CONSECUTIVE YEARS. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will at least annually measure, evaluate, and report to the medical staff and governing body, the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 4. Requirements for approval -- all applicants for adult open heart surgery services

Sec. 4. (3) An applicant proposing to initiate adult (non-pediatric) open heart surgery as a new service shall demonstrate that 300 adult open heart surgical CASESprocedures BASED ON result from application of the methodology SET FORTHdescribed in Section 8.

Section 5. Requirements for approval -- all applicants for pediatric open heart surgery services

Sec. 5. (4) An applicant proposing to initiate pediatric open heart surgery as a new service shall demonstrate that 100 pediatric open heart surgical CASESprocedures BASED ONresult from application of the methodology SET FORTHdescribed in Section 9.

SECTION 4. REQUIREMENTS FOR APPROVAL FOR APPLICANTS PROPOSING TO ACQUIRE AN EXISTING OPEN HEART SURGERY SERVICE

SEC. 4. AN APPLICANT PROPOSING TO ACQUIRE A HOSPITAL THAT HAS BEEN APPROVED TO PERFORM OPEN HEART SURGERY SERVICES MAY ALSO ACQUIRE THE EXISTING OPEN HEART SURGERY SERVICE IF IT CAN DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(1) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS ON THE DATE OF ACQUISITION. THE OPEN HEART SURGERY SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE DATE THE SERVICE IS ACQUIRED, AND ANNUALLY THEREAFTER.

(2) EXCEPT AS PROVIDED FOR IN SUBSECTION (1), AN APPLICATION FOR THE ACQUISITION OF AN EXISTING OPEN HEART SURGERY SERVICE AFTER THE EFFECTIVE DATE OF THESE STANDARDS SHALL BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS, AS SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS, ON THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE APPLICANT AGREES TO OPERATE THE OPEN HEART SURGERY SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 7 OF THESE STANDARDS.

SECTION 5. REQUIREMENTS FOR ALL APPLICANTS

SEC 5. AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES, IF A CON IS APPROVED.

Section 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart surgery services shall not use any of its adult MIDB data in support of any other application for adult open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. -AFTER THE 7-YEAR PERIOD:

(A) A HOSPITAL(S) MAY ONLY COMMIT ITS ADULT MIDB DATA IN SUPPORT OF ANOTHER APPLICATION FOR ADULT OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN HEART SURGERY SERVICES, OR;

(B) A HOSPITAL THAT HAS EXPERIENCED AN INCREASE IN ITS ADULT MIDB DATA AND WANTS TO START ITS OWN PROGRAM, THEN THE HOSPITAL MAY USE ONLY ITS ENTIRE PROJECTED VOLUME (PREVIOUSLY COMMITTED MIDB DATA PLUS THE INCREASE OF ADULT MIDB DATA) TO SUPPORT ITS OWN APPLICATION TO INITIATE AN OPEN HEART SURGERY SERVICE.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric open heart surgery services shall not use any of its pediatric MIDB data in support of any other

application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support. AFTER THE 7-YEAR PERIOD:

(A) A HOSPITAL(S) MAY ONLY COMMIT ITS PEDIATRIC MIDB DATA IN SUPPORT OF ANOTHER APPLICATION FOR PEDIATRIC OPEN HEART SURGERY SERVICES IF THEY HAVE EXPERIENCED AN INCREASE FROM THE PREVIOUSLY COMMITTED MIDB DATA. ONLY THAT ADDITIONAL INCREASE IN MIDB DATA CAN BE COMMITTED TO ANOTHER APPLICANT TO INITIATE OPEN HEART SURGERY SERVICES, OR;

(B) A HOSPITAL THAT HAS EXPERIENCED AN INCREASE IN ITS PEDIATRIC MIDB DATA AND WANTS TO START ITS OWN PROGRAM, THEN THE HOSPITAL MAY USE ONLY ITS ENTIRE PROJECTED VOLUME (PREVIOUSLY COMMITTED MIDB DATA PLUS THE INCREASE OF PEDIATRIC MIDB DATA) TO SUPPORT ITS OWN APPLICATION TO INITIATE AN OPEN HEART SURGERY SERVICE.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart surgery service or have a valid CON issued under ~~former Part 221 or~~ Part 222 to operate an adult or pediatric open heart surgery service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231~~(9)~~ of the Code, being Section 333.22231~~(9)~~ of the Michigan Compiled Laws.

Section 7. Project delivery requirements -- terms of approval for all applicants

Sec. 7. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following quality assurance standards:

(i) The open heart surgery service shall be operating at an annual level of 300 adult open heart surgical CASES~~procedures~~ or 100 pediatric open heart surgical CASES~~procedures~~, as applicable, by the end of the third 12 full months of operation, AND ANNUALLY THEREAFTER.

(ii) Each physician credentialed by the applicant hospital to perform adult open heart surgery CASES~~procedures~~, as the attending surgeon, shall perform a minimum of 75~~50~~ adult open heart surgery CASES~~procedures~~ per year. The annual case load for a physician means adult open heart surgery CASES~~procedures~~ performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.

(iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.

(iv) The service shall have the capability for rapid mobilization of a cardiac surgical team for emergency CASES~~procedures~~ 24 hours a day, 7 days a week.

(v) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(d) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(i) provide open heart surgery services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment; and

(ii) maintain information by source of payment to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(e) The applicant shall prepare and present to the medical staff and governing body reports describing activities in the open heart surgery service including complication rates and other morbidity and mortality data.

(f) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include but is not limited to annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(G) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES. THE DEPARTMENT OR ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT SUBMIT A SUMMARY REPORT AS SPECIFIED BY THE DEPARTMENT. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA IN A FORMAT ESTABLISHED BY THE DEPARTMENT OR ITS DESIGNEE. THE APPLICANT SHALL BE LIABLE FOR THE COST OF DATA SUBMISSION AND ON-SITE REVIEWS IN ORDER FOR THE DEPARTMENT TO VERIFY AND MONITOR VOLUMES AND ASSURE QUALITY. THE APPLICANT SHALL BECOME A MEMBER OF THE DATA REGISTRY SPECIFIED BY THE DEPARTMENT UPON INITIATION OF THE SERVICE. PARTICIPATION SHALL CONTINUE ANNUALLY THEREAFTER. THE OUTCOMES DATABASE MUST UNDERGO STATEWIDE AUDITING.

(H) AN APPLICANT THAT FAILS TO COMPLY WITH THE QUALITY ASSURANCE STANDARDS UNDER SUBSECTION (C) SHALL BE REQUIRED TO PROVIDE ITS QUALITY AND RISK ADJUSTED OUTCOMES DATA FROM THE DATA REGISTRY TO THE DEPARTMENT, OR ITS DESIGNEE, AS PART OF THE DEPARTMENT'S ENFORCEMENT AND COMPLIANCE ACTIVITIES.

(~~g~~l) The applicant shall provide the Department with a notice stating the date on which the first approved service is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) The agreements and assurances required by this section shall be in the form of a certification AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT~~authorized by the governing body of the applicant~~.

Section 8. Methodology for computing the number of adult open heart surgical CASES~~procedures~~

Sec. 8. (1) An applicant shall apply the methodology set forth in this section for computing the number of adult open heart surgical CASES~~procedures~~. In applying discharge data in the methodology, each applicable inpatient record shall be used only once. This methodology shall utilize only the inpatient discharges that have one or more of the cardiac diagnoses in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall identify the discharges that were from patients aged 15 years and older. These discharges shall be considered "adult discharges."

(b) Using the "adult discharges" identified in Subdivision (a), an applicant shall count the number of discharges with a principal diagnosis corresponding to each of the first six categories (Groups A through F) of ICD-9-CM codes listed in Subsection (2). When a patient has a principal diagnosis which falls into one of these six groups (exclude Other Heart Conditions), then they shall be categorized by that diagnosis and their case shall be removed from the data to be used in Subdivisions (c), (d) and (e) so that each applicable inpatient record shall be counted only once.

(c) The procedure in this subdivision shall be used to determine in which diagnosis group each appropriate inpatient record is to be included. The first four non-principal diagnosis codes shall be used to determine the categorization of the remaining records. The sequence of the ICD-9-CM groupings in Subsection (2) shall be followed exactly. For each individual inpatient record, an applicant shall start with

the first category of Valves (Group A: ICD-9-CM codes 394.0-397.99 and 424.0-424.99) and shall search through the first four non-principal diagnosis codes to determine if any fall into this grouping. If a record has a non-principal diagnosis code for this grouping, it shall be assigned to the Valve gGroup A and shall be removed from all subsequent search actions. The remaining inpatient records shall then be searched for the presence of the ValveGROUP A codes. After all the inpatient records with Valve codesGROUP A have been removed, the above procedure shall be repeated for each of the remaining five groups (Groups B through F) in sequence. For example: the next step would be a search of remaining inpatient records for codes representing the Congenital Anomalies (Group B: ICD-9-CM codes 745.0-747.99). NOTE: The above procedure shall not apply to the All Other Heart Conditions category (Group G).

(d) Add the count of the number of records for each principal diagnosis group (separately) that was identified under Subdivision (b) with the count of the number of records for its respective non-principal diagnosis group identified under Subdivision (c). The end result shall be a total count for each of the first six diagnostic groups (excluding All Other Heart Conditions - Group G).

(e) Using the remaining discharge data, an applicant shall count the discharges that were from patients that have a principal diagnosis or any of the first four non-principal diagnoses using the ICD-9-CM codes for the All Other Heart Conditions category (Group G) listed in Subsection (2).

(f) An applicant shall multiply the count for each ICD-9-CM category listed in Subsection (2) by its corresponding Adult Open Heart Utilization Weight and add the products together to produce the number of adult open heart surgical CASESprocedures for the applicant.

(2) For purposes of the adult open heart methodology, the following cardiac diagnoses shall be used:

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES~~PROCEDURES~~

Group	Major ICD-9-CM Code Group	Category	Adult Open Heart Utilization Weights
~~A~~	~~394 - 397.9~~ ~~424 - 424.99~~	~~Valves~~	~~.0808~~
AB~~B~~	745 - 747.99	Congenital Anomalies	.125246~~.0766~~
B	394 – 397.9 424 – 424.99	VALVES	.086804
C	410 – 410.99	ACUTE MYOCARDIAL INFARCT	.071210
D~~C~~	414 - 414.99	Other Chronic Ischemic	.062683~~.0632~~
E~~D~~	411 - 411.99	Other Acute & Sub Acute Ischemic	.012538~~.0510~~
~~E~~	~~410 - 410.99~~	~~Acute Myocardial Infarct~~	~~.0400~~
F	413 - 413.99 786.5 - 786.59	Angina & Chest Pain	.000546~~.0102~~
G	164.1, 212.7 390 - 393 398 - 405.99 412, 415 - 423.9 425 - 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51, 901.0 996.02, 996.03	All Other Heart Conditions	.002085~~.0029~~

(3) The major ICD-9-CM groupings and Open Heart utilization weights in Subsection (2) are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS~~former Division of Planning and Policy Development~~, Michigan Department of COMMUNITY~~Public~~ Health, utilizing the 2005~~1986~~ Michigan Inpatient Data Base.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical CASES~~procedures~~

Sec. 9. (1) An applicant shall apply the methodology set forth in this section for computing the number of pediatric open heart surgical CASES~~procedures~~. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall count the discharges that were from

patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Subsection (2). Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Other Heart" category in Subsection (2). Discharge records which do not have one or more of the Other Heart codes listed in Subsection (2) shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "Other Heart" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical CASES~~procedures~~ for the applicant.

(2) For purposes of the pediatric open heart methodology, the following diagnoses shall be used:

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES~~PROCEDURES~~

Major ICD-9-CM Grouping	Category	Pediatric Open Heart Utilization Weights
745.0-747.99	Congenital Anomalies	.210888~~.1286~~
164.1, 212.7 390-429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0, 996.02	Other Heart	.042973~~.0147~~

(3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights are based on the work of the BUREAU OF HEALTH POLICY, PLANNING AND ACCESS~~former Division of Planning and Policy Development~~, Michigan Department of COMMUNITY~~Public~~ Health, utilizing the 2005~~1986~~ Michigan Inpatient Data Base.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING AREA			
1	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
2	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE

3	BARRY	CALHOUN	ST. JOSEPH
	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
4	ALLEGAN	MASON	NEWAYGO
	IONIA	MECOSTA	OCEANA
	KENT	MONTCALM	OSCEOLA
	LAKE	MUSKEGON	OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE
6	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	

~~7~~	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

~~**Section 11. Application of Rule 325.9403**~~

~~Sec. 11. (1) Pursuant to CON rule 325.9403, a CON for open heart surgery services approved under these standards or standards that became effective on December 5, 1988 shall expire 1 year from its effective date, unless the project is initiated. One 6-month extension may be granted by the Department if the applicant shows that substantial progress toward initiation of the approved open heart surgery service has been made and an obligation for capital expenditure, if any, will occur within the extended time period.~~

~~(2) For purposes of open heart surgery services, "initiated" means when the first open heart surgery procedure is performed.~~

Section 11~~12~~. Effect on prior planning policies; comparative reviews

Sec. 11~~12~~. (1) These CON Review Standards supersede and replace the CON Review Standards for Open Heart Surgery Services approved by the CON Commission on MARCH 9, 2004~~March 11, 2003~~ and effective on JUNE 4, 2004~~May 12, 2003~~.

~~(2) Hospitals recognized by the Department pursuant to the prior State Medical Facilities Plan (SMFP) 1985-90 Planning Policies Pertaining to Cardiac Services as "Level II" cardiac service providers shall not be considered open heart surgery services providers as defined in Section 2. Those hospitals recognized by the Department as Level II providers under Part 221 may continue to provide Level II cardiac services consistent with the 1985-90 State Medical Facilities Plan.~~

~~(~~2~~3~~) Projects reviewed under these standards shall not be subject to comparative review.

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: September 17, 2007

TO: Irma Lopez

FROM: Andrea Moore

RE: Summary of Public Hearing Testimony on Proposed Air Ambulance Standards

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The Department gave its report to the Commission on the review of the Air Ambulance Services Standards at the June 13, 2007 Commission Meeting. The Commission accepted the Department's report and took proposed action on the draft changes to the Standards.

Accordingly, the Department held a Public Hearing on August 1, 2007 on the proposed Air Ambulance Services Standards. Written testimony was accepted via the Department website for an additional 7 days after the hearing. Testimony was received from five (5) facilities and is summarized as follows:

1. Aero Med Spectrum Health
   - Reinstate the references to critical care or specialty care support services within the definitions section.
   - Modify the volume requirement within the expansion section to require that at least half of the air ambulance service volume would be from patient transports.
   - Addition of a separate section to allow for a change in base of operations of an air ambulance service. The service would not be required to stay within the same Medical Control Authority.

2. Michigan Association of Air Medical Services
   - Reinstate the references to critical care or specialty care support services within the definitions section.
   - Modify the volume requirement within the expansion section to require that at least half of the air ambulance service volume would be from patient transports.

3. Midwest Med flight
   - Supports recommended changes submitted by Spectrum Health.
   - Addition of a separate section to allow for a change in base of operations of an air ambulance service. The service would not be required to stay within the same Medical Control Authority.

4. North Flight, Inc.
   - Supports the Standards as drafted.

5. University of Michigan
   - Reinstate the references to critical care or specialty care support services within the definitions section.
   - Modify the definition of Organ Transport by allowing it to include either the transport of an organ or the transplant team, not specifically both. Additionally, remove the requirement that it is occurring in Michigan.
   - Modify the volume requirement within the expansion section to require that at least half of the air ambulance service volume would be from patient transports.
   - Addition of a separate section to allow for a change in base of operations of an air ambulance service. The service would not be required to stay within the same Medical Control Authority.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve a urinary extracorporeal shock wave lithotripsy service/unit.

(2) Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, ~~9,~~ 12, 13, 14, and 15, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use sections 10 and 11, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 9 IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of an existing UESWL service OR EXISTING UESWL UNIT(S)" means obtaining possession or control of an existing FIXED OR MOBILE UESWL service ~~and its~~OR EXISTING UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.

(b) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

(f) ~~"Comprehensive kidney stone treatment center" or "CKSTC" means a facility that employs a multi-dimensional approach to the treatment of kidney stones. In addition to a lithotripsy unit, a CKSTC uses holmium lasers, urology endoscopes, ultrasonic, and electrohydraulic stone devices to perform cystoscopies, ureteroscopies, and nephrostolithotomies. A CKSTC has service availability 24 hours a day. Its medical staff is drawn from a multi-county area or is comprised of full-time medical school faculty. A CKSTC has a medical education program that has surgical residents. A CKSTC serves as source of expertise and rarely-used kidney stone devices for other local providers.~~

~~(g)~~ "Department" means the Michigan Department of Community Health (MDCH).

(G) "EXISTING MOBILE UESWL UNIT" MEANS A CON-APPROVED AND OPERATIONAL UESWL UNIT AND TRANSPORTING EQUIPMENT OPERATED BY A CENTRAL SERVICE COORDINATOR THAT PROVIDES UESWL SERVICES TO TWO OR MORE HOST SITES.

(H) "EXISTING UESWL SERVICE" MEANS THE UTILIZATION OF A CON-APPROVED AND OPERATIONAL UESWL UNIT(S) AT ONE SITE IN THE CASE OF A FIXED UESWL SERVICE OR AT EACH HOST SITE IN THE CASE OF A MOBILE UESWL SERVICE.

(~~h~~I) "Existing UESWL unit" means THE UTILIZATION OF A CON-APPROVED AND OPERATIONAL ~~a~~ UESWL unit ~~that has CON approval to operate in Michigan and is in operation on the date an application is submitted to the Department~~.

(~~i~~J) "Expand aN EXISTING UESWL service" means the addition of one UESWL unit at an existing UESWL service.

(~~j~~K) "Hospital" means a health facility licensed under Part 215 of the Code.

(~~k~~L) "Host site" means the site at which a mobile UESWL unit is authorized to provide UESWL services.

(~~l~~M) "Initiate a UESWL service" means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or relocation of an existing UESWL service or the renewal of a lease.

(~~m~~N) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

(~~n~~O) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(~~o~~P) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.

(~~p~~Q) "Michigan Inpatient Database" or "MIDB" means the database that is compiled by the Michigan Health and Hospital Association or successor organization. The database consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(~~q~~R) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.

(~~r~~S) "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(~~s~~T) "Planning area" means the state of Michigan.

(~~t~~U) "Region" means the geographic areas set forth in Section 12.

(V) "RELOCATE A FIXED UESWL UNIT" MEANS A CHANGE IN THE LOCATION OF A FIXED UESWL UNIT(S) FROM THE EXISTING SITE TO A DIFFERENT SITE WITHIN THE RELOCATION ZONE.

(~~u~~W) "Relocate an existing UESWL service" means a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.

(~~v~~X) "Relocation zone~~,~~" ~~for purposes of these standards,~~ means the geographic area that is within a 25-mile radius, within the state of Michigan, of the existing site of the UESWL service to be relocated.

(~~w~~Y) "Renewal of a lease" means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 2(1)(X), or a change in the parties to the lease.

(~~x~~Z) "Replace~~/upgrade~~ aN EXISTING UESWL unit" means aN EQUIPMENT change ~~involving all or part~~ of an existing UESWL unit, OTHER THAN AN UPGRADE, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. THE TERM DOES NOT INCLUDE AN UPGRADE OF AN EXISTING UESWL UNIT, CHANGING A MOBILE UESWL UNIT TO A FIXED UESWL UNIT, OR CHANGING A FIXED UESWL UNIT TO A MOBILE UESWL UNIT.

(~~y~~AA) "Retreatment" means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of

a mobile service, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.

(~~z~~BB) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

(CC) "UPGRADE AN EXISTING UESWL UNIT" MEANS ANY EQUIPMENT CHANGE, OTHER THAN A REPLACEMENT, THAT INVOLVES A CAPITAL EXPENDITURE OF $125,000 OR LESS IN ANY CONSECUTIVE 24-MONTH PERIOD.

(~~aa~~DD) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the ureter by means of an endoscope~~,~~ that may or may not include laser technology.

(~~bb~~EE) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract.

(FF) "UESWL SERVICE" MEANS EITHER THE CON-APPROVED UTILIZATION OF A UESWL UNIT(S) AT ONE SITE IN THE CASE OF A FIXED UESWL SERVICE OR AT EACH HOST SITE IN THE CASE OF A MOBILE UESWL SERVICE.

(~~cc~~GG) ~~"Urinary extracorporeal shock wave lithotripter" or~~ "UESWL unit" means the medical equipment that produces the shock waves for the UESWL procedure.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for APPROVAL FOR all applicants proposing to initiate a urinary extracorporeal shock wave lithotripsy service

Sec. 3. (1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:

(a) The capability to provide complicated stone disease treatment on-site.

(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 13(1).

(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:

(i) On-call availability of an anesthesiologist and a surgeon.

(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.

(iii) On-site IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.

(iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.

(v) On-site crash cart.

(vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit.

(vii) On-site 23-hour holding unit.

Section 4. Requirements for approval for applicants proposing to replace~~/upgrade~~ aN EXISTING UESWL unit(s)

Sec. 4. (1) An applicant proposing to replace~~/upgrade~~ an existing UESWL unit(s) shall demonstrate the following~~, as applicable~~:

(a) ~~The~~ EACH EXISTING UESWL unit OF THE SERVICE PROPOSING TO REPLACE A UESWL UNIT ~~proposed to be replaced/upgraded~~ has ~~performed~~ AVERAGED at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the Department has verifiable data.

(b) Each UESWL unit ~~at the same site~~OF THE SERVICE PROPOSING TO REPLACE A UESWL UNIT is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 13.

(2) An applicant proposing to replace~~/upgrade~~ a UESWL unit shall demonstrate one or more of the

following:

(a) The existing equipment clearly poses a threat to the safety of the public.

(b) The proposed replacement~~/upgraded~~ UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.

(C) THE EXISTING EQUIPMENT IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES.

(3) An applicant that demonstrates that it meets the requirements in THIS ~~subdivision~~SUBSECTION ~~(a), (b), or (c) of this subsection~~ shall not be required to demonstrate compliance with Section 4(1):

(a)~~(i)~~ The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.

(~~ii~~B) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.

(~~iii~~C) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 13 are combined for the following, as applicable:

(~~A~~I) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, that are located in the region identified in ~~subdivision~~SUBSECTION (~~iii~~C).

(~~B~~II) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in ~~subdivision~~SUBSECTION (~~iii~~C).

(~~iv~~D) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.

(~~v~~E) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 13.

~~(b)(i) The proposed project involves replacing 2 or more existing fixed UESWL units with 1 mobile UESWL unit.~~

~~(ii) The applicant entity is either: a single organization that operates a fixed UESWL service or a joint venture or other arrangement between at least 2 or more organizations that each operates a fixed UESWL service on the date an application is submitted to the Department.~~

~~(iii) The proposed mobile UESWL service will serve at least 1 host site that is located in a region other than the region or regions in which the fixed UESWL units proposed to be replaced are located currently.~~

~~(iv) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 13 are combined for the following, as applicable:~~

~~(A) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, that are located in the region identified in subdivision (iv).~~

~~(B) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subdivision (iv).~~

~~(v) A separate application from each host site is filed at the same time the application to replace the fixed units is submitted to the Department.~~

~~(vi) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 13.~~

~~(c)(i) The proposed project involves replacing 3 or more existing fixed UESWL units with 1 UESWL unit, either fixed or mobile.~~

~~(ii) The applicant entity is a joint venture or other arrangement among 3 or more organizations that each operates a fixed UESWL service on the date an application is submitted to the Department.~~

~~(iii) The combined number of UESWL procedures performed by all of the fixed UESWL units operated by the organizations that are party to the applicant entity is equal to or greater than 1,000 procedures based on the methodology set forth in Section 13.~~

~~(4) An applicant that operates a fixed or mobile UESWL unit that is proposing a project involving the replacement/upgrade of an existing UESWL unit, when the capital costs for that replacement/upgrade are $125,000 or less, shall not be required to meet the requirements of subsection (1). This subsection shall apply to the review and decision on only 1 application for the replacement/upgrade of each UESWL unit~~

~~and on only 1 application at each site.~~

(~~5~~4) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

~~(6) An applicant which can demonstrate that it is a CKSTC with a fixed UESWL unit shall not be required to meet the requirements of Section 4(1) if it can demonstrate the following:~~
~~(a) The CKSTC has performed at least 2,000 kidney stone treatment procedures during the most recent continuous 12-month period. For the purpose of this subsection, comprehensive kidney stone treatment procedures shall be calculated as the sum of the cystoscopies (ICD-9-CM codes 57.32 and 57.33), nephrostolitohtomies (ICD-9-CM codes 55.03 and 55.04), ureteroscopies (ICD-9-CM codes 56.0, 56.31, and 56.33), and UESWL (ICD-9-CM code 98.51) procedures performed at the CKSTC during the most recent continuous 12-month period.~~
~~(b) Of the comprehensive kidney stone treatment procedures performed during the most recent continuous 12-month period, at least 600 must have been UESWL procedures.~~

Section 5. Additional requirements for approval for mobile UESWL services

Sec. 5. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:

(a) The proposed mobile UESWL service meets the requirements of Section 3 or 4, as applicable.

(b) AT LEAST 100 UESWL PROCEDURES ARE PROJECTED IN EACH REGION IN WHICH THE PROPOSED MOBILE UESWL UNIT IS PROPOSING TO OPERATE WHEN THE RESULTS OF THE METHODOLOGY IN SECTION 13 ARE COMBINED FOR THE FOLLOWING, AS APPLICABLE:

(I) ALL LICENSED HOSPITAL SITES COMMITTING MIDB DATA PURSUANT TO SECTION 14, AS APPLICABLE, ARE LOCATED IN THE REGION(S) IDENTIFIED IN SUBSECTION (B).

(II) ALL SITES THAT RECEIVE UESWL SERVICES FROM AN EXISTING UESWL UNIT AND PROPOSE TO RECEIVE UESWL SERVICES FROM THE PROPOSED MOBILE UNIT ARE LOCATED IN THE REGION(S) IDENTIFIED IN SUBSECTION (B).

(C) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator.

(2) The requirements of subsection (1)(a) AND (1)(B) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural or micropolitan statistical area county.

(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.

(c) A separate CON application has been submitted by the CSC and each proposed host site.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).

(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 13 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, ~~that~~ are located in that region(S).

(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) ~~and that~~ are located in that region(S).

Section 6. Requirements for approval for applicants proposing to acquire an existing UESWL service and its unit(s) OR AN EXISTING UESWL UNIT(S)

Sec. 6. (1) An applicant proposing to acquire an existing fixed or mobile UESWL service and its unit(s) shall demonstrate that a proposed project meets all of the following:

(~~1~~A) The ~~project will not result in the replacement of the UESWL unit at the UESWL service to be acquired unless the applicant demonstrates that the~~ requirements of ~~Section~~ SectionS 4 AND 7, as applicable, ~~also~~ have been met.

~~(2) The project will not result in a change in the site at which the existing UESWL service and its unit(s) is operated unless the proposed project meets the requirements of Section 7.~~

(~~3~~B) For an application for the proposed first acquisition of an existing fixed or mobile UESWL service, for which a final decision has not been issued after ~~the effective date of these standards~~MAY 2, 1998, an existing UESWL service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 10 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

(~~4~~C) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first application approved pursuant to subsection (3), for which a final decision has not been issued after ~~the effective date of these standards~~MAY 2, 1998, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed AN AVERAGE OF at least 1,000 procedures PER UNIT in the most recent 12-month period for which the Department has verifiable data.

(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING FIXED OR MOBILE UESWL UNIT(S) OF AN EXISTING UESWL SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE REQUIREMENTS OF SECTION 4 AND 7, AS APPLICABLE, HAVE BEEN MET.

(B) FOR ANY APPLICATION FOR PROPOSED ACQUISITION OF AN EXISTING FIXED OR MOBILE UESWL UNIT(S), AN APPLICANT SHALL BE REQUIRED TO DEMONSTRATE THAT THE UESWL UNIT(S) TO BE ACQUIRED PERFORMED AN AVERAGE OF AT LEAST 1,000 PROCEDURES PER UNIT IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(C) THE REQUIREMENTS OF SECTION 3(1)(C) HAVE BEEN MET.

Section 7. Requirements for approval for applicants proposing to relocate an existing UESWL service AND/OR UESWL UNIT(S)

Sec. 7. (1) An applicant proposing to relocate its existing UESWL service and its unit(s) shall demonstrate that the proposed project meets all of the following:

(~~1~~A) The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).

(~~2~~B) The UESWL service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(~~3~~C) The ~~proposed project will not result in the replacement of the UESWL unit(s) of the service to be relocated unless the applicant demonstrates that the~~ requirements of ~~Section~~ SectionS 4 AND 8, as applicable, ~~also~~ have been met.

~~(4) The proposed project will not result in an increase in the number of fixed unit(s) being operated by the UESWL service that is proposed to be relocated.~~

(~~5~~D) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).

(~~6~~E) The proposed NEW site ~~to which the UESWL service is proposed to be relocated~~ is in the relocation zone.

(~~7~~F) The UESWL service and its unit(s) to be relocated performed AN AVERAGE OF at least 1,000 procedures PER UNIT in the most recent 12-month period for which the Department has verifiable data.

(~~8~~G) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 10 of these standards.

(2) AN APPLICANT PROPOSING TO RELOCATE A FIXED UESWL UNIT(S) OF AN EXISTING

UESWL SERVICE SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING:

(A) THE EXISTING UESWL SERVICE FROM WHICH THE UESWL UNIT(S) IS TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(B) THE REQUIREMENTS OF SECTIONS 4 AND 8, AS APPLICABLE, HAVE BEEN MET.

(C) THE SITE TO WHICH THE UESWL UNIT(S) WILL BE RELOCATED MEETS THE REQUIREMENTS OF SECTION 3(1)(C).

(D) THE PROPOSED NEW SITE IS IN THE RELOCATION ZONE.

(E) EACH EXISTING UESWL UNIT(S) AT THE SERVICE FROM WHICH A UNIT IS TO BE RELOCATED PERFORMED AT LEAST AN AVERAGE OF 1,000 PROCEDURES PER FIXED UNIT IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

(F) THE APPLICANT AGREES TO OPERATE THE UESWL UNIT(S) IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 10 OF THESE STANDARDS.

Section 8. Requirements FOR APPROVAL to expand aN EXISTING UESWL service ~~-- all applicants~~

Sec. 8. An applicant proposing to expand aN EXISTING UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:

(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.

(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 13 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.

(3) An applicant proposing to expand aN EXISTING mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 5(1)(~~B~~C).

Section 9. Requirements for approval ~~- --~~ all applicants

Sec. 9. An applicant shall provide verification of Medicaid participation ~~at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department~~ AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICE IF A CON IS APPROVED.

Section 10. Project delivery requirements -- terms of approval for all applicants

Sec 10. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following quality assurance standards:

(i) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service

coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(ii) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.

(iii) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(iv) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(v) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.

(vi) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(vii) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of ~~subdivision~~SUBSECTION (vi), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(viii) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

(ix) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) Not deny UESWL services to any individual based on inability to pay or source of payment,

(B) Provide UESWL services to any individual based on clinical indications of need for the services, and

(C) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(x) An applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

(xi) The applicant shall provide the Department with a notice stating the date the approved UESWL service and its unit(s) is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(2) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE UESWL SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.~~

(3) ~~The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~ THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

Section 11. Project delivery requirements - additional terms of approval for applicants involving mobile UESWL services

Sec. 11. (1) In addition to the provisions of Section 10, an applicant for a mobile UESWL service shall agree that the services provided by the mobile UESWL unit(s) shall be delivered in compliance with the following terms of CON approval:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) ~~Each~~ IF THE host site WILL NOT BE PERFORMING THE LITHOTRIPSY PROCEDURES INSIDE THE FACILITY, IT must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

(2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the governing body of~~AGREED TO BY the applicant or its authorized agent.

Section 12. Regions

Sec. 12. The counties assigned to each region are as follows:

Region				
1	Livingston	Monroe	Macomb	Oakland
	St. Clair	Washtenaw	Wayne	
2	Clinton	Eaton	Hillsdale	Ingham
	Jackson	Lenawee		
3	Barry	Berrien	Branch	Calhoun
	Cass	Kalamazoo	St. Joseph	Van Buren
4	Allegan	Ionia	Kent	Lake
	Mason	Mecosta	Montcalm	Muskegon
	Newaygo	Oceana	Osceola	Ottawa
5	Genesee	Lapeer	Shiawassee	
6	Arenac	Bay	Clare	Gladwin
	Gratiot	Huron	Iosco	Isabella
	Midland	Ogemaw	Roscommon	Saginaw

		Sanilac	Tuscola		
	7	Alcona	Alpena	Antrim	Benzie
		Crawford	Charlevoix	Cheboygan	Emmet
		Gd. Traverse	Kalkaska	Leelanau	Manistee
		Missaukee	Montmorency	Oscoda	Otsego
		Presque Isle	Wexford		
	8	Alger	Baraga	Chippewa	Delta
		Dickinson	Gogebic	Houghton	Iron
		Keweenaw	Luce	Mackinac	Marquette
		Menominee	Ontonagon	Schoolcraft	

Section 13. Methodology for projecting UESWL procedures

Sec. 13. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 14. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL unit, EXCEPT FOR INITIATION, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

Section 14. Requirements for MIDB data commitments

Sec. 14. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.

(b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in ~~subdivision~~SUBSECTION (1)(a).

(c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

Section 15. Effect on prior planning policies; comparative reviews

Sec. 15. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~September 21, 2001~~MARCH 9, 2004 and effective on ~~November 26, 2001~~JUNE 4, 2004.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 13(1)(b) used for calculating the projected number of UESWL procedures shall be ~~1.02~~.

(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:

(a) Steps for determINing preliminary statewide UESWL adjustment factor:

(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 for the most recent year for which Michigan Inpatient Database information is available to the Department.

(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.

(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.

(b) Steps for determining urban/rural adjustment factor:

(i) For each hospital, assign urban/rural status based on the 2000 census. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) The records from step (a)(i) above will then be aggregated by "urban/rural" and zip code.

(iii) Zip codes that are totally "urban" or "rural" will have the discharges and populations aggregated for those respective groups.

(iv) For the remaining zip codes with both "urban" and "rural" components, the proportion of the zip code in each part (urban or rural) will be calculated and applied to the population for that zip code.

(v) These will then be aggregated by discharge and population by urban/rural status.

(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately per 10,000 population.

(vii) The percentage difference between "urban" and "rural" discharge rates will be applied to the rate identified in step (a)(iii) above. The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

APPENDIX B

CON REVIEW STANDARDS FOR UESWL SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

Date: September 15, 2007
To: Michigan Certificate of Need Commission
From: Daniel B. Shumaker, MD FACR.
Chair, CT Standards Advisory Committee

Dear Commissioners,

As required of the Chair of the Computed Tomography Standards Advisory Committee (CT SAC), I respectfully submit an interim report on the committee's work.

The CT SAC has met three times and has two remaining meetings scheduled in October and November. A substantial amount of progress has been made, however we are in the process of scheduling a third meeting, should it be necessary, to ensure that our final report will be ready for submission at the December Commission meeting.

In addition to the foundational question of whether CT should remain under CON regulation as a covered clinical service, the CT SAC was given 10 separate charges to consider by the Commission. We have taken tentative action on 8 of those charges. When we have completed our consideration of the 2 which remain before us, we will take final action on all of the charges and present our final report in December. I will address each of the charges in the order in which they appear on the charge list approved by the Commission on March 13, 2007.

The foundational question:

The CT SAC recommends that CT continues to be regulated by CON as a covered clinical service.

Charge 1.) Review volume commitment numbers (actual, projected, and thresholds).

The CT SAC recommends no change in the current volume commitment numbers.

Charge 2.) Review relocation criteria and definition, i.e., unit vs. service similar to recent changes in other CON review standards.

The CT SAC recommends that a CT scanner, as opposed to "a service" in the current standards, may be relocated. All other relocation requirements in the current standards remain unchanged.

Charge 3.) Review replace/upgrade criteria and definitions.

The CT SAC recommends no change in the current requirements. However, for scanners currently in use which are not meeting volume thresholds required for upgrade or replacement, the CT SAC recommends, if desired, a one time upgrade or replacement of the scanner if it meets the following criteria:

- The scanner at one time met the required volume threshold.
- The scanner is currently operating at, or above, 5000 CT equivalents per year.
- The scanner is fully depreciated.

The current standards would apply for any future upgrade or replacement of the scanner.

Charge 4.) Review commitment process; make them similar to MRI and PET.

No action has been taken.

Charge 5.) Review criteria and processes for addressing emerging specialty use scanners (e.g., dental, "mini", portable, and hybrid).

No action has been taken.

Charge 6.) Review potential pediatric and special needs criteria and need for specific weighting.

The CT SAC recommends that the CT standards adopt language similar to that of the MRI standards:

- Add a section to the standards which would define criteria for a "special pediatric facility" and dedicated pediatric CT scanner.
- Adopt pediatric weighting for the calculation of CT equivalents, as in the MRI standards, which recognize the additional time and care involved in imaging the pediatric patient.
- Recommend physician familiarity with the ALARA principle of dosimetry, and proper tailoring of imaging protocols in pediatric patients to limit the radiation dose.

Charge 7.) Review use of commitments from neighboring states.

The CT SAC recommends acceptance of technical changes in the language suggested by the Department.

Charge 8.) Review CT scanner use in simulation MRT.

The CT SAC recommends acceptance of technical changes in the language suggested by the Department.

Charge 9. Technical changes in language to be uniform with other CON standards.

The CT SAC recommends acceptance of technical changes in the language suggested by the Department.

Charge 10.) Other items may be considered by the SAC Chairperson, if appropriate, at the initial meeting of the SAC. Consideration of additional items by the SAC shall not affect the established deadline for the SAC of December 11, 2007.

The CT SAC did not identify additional items to consider at its initial meeting.

I would personally like to compliment the Department staff for their assistance and management of the meetings.

This concludes the interim report of the CT SAC. When I present the final report at the December Commission meeting, I will be prepared to discuss the rationale for action taken on each of the individual charges. If, however, you have questions in the interval, please do not hesitate to contact me.

Respectfully,

Daniel B. Shumaker, MD FACR
Chair, CT Standards Advisory Committee

Since the last CON meeting, there were two New Medical Technology Advisory Committee (NEWTAC) meetings.

At the first meeting on August 14, 2007, there was a discussion regarding the committee's responsibility to review new medical technology no later than one year after gaining FDA approval. As such, the committee reviewed the devices approved by the FDA during the second quarter of 2007. Consequently, NEWTAC did not see a need for any of these devices needed to be under CON jurisdiction.

Also at this meeting, there was a discussion of the CON commission's request for NEWTAC to evaluate whether or not interventional neuroradiology and/or vascular surgery should be added to the list of regulated services. Dr. Suresh Mukherji, Professor and Chief of Neuroradiology at the University of Michigan, presented on the topic of interventional neuroradiology. Dr. Mukherji revealed that interventional neuroradiology actually consists of both diagnostic and therapeutic services. Since the state lacks outpatient data and some of these procedures are done as outpatient, Dr. Keshishian obtained BCBSM/BCN inpatient and outpatient data for these services. In 2006, approximately 11,000 diagnostic procedures were done on BCBSM/BCN members while fewer than 1,000 therapeutic procedures were performed within the same year.

At the August 28, 2007 meeting, NEWTAC continued discussion of interventional neuroradiology before voting as whether or not these services should fall under CON management. The New Medical Technology Advisory Committee heard testimony that only a small fraction of the interventional neuroradiology services are therapeutic that these are being done by only a few, highly skilled physicians only at the facilities with the most advanced equipment. With a vote of 9-3, the committee recommends that interventional neuroradiology not be under CON regulation.

Additionally, the committee began to investigate vascular surgery. They requested additional information for the next meeting concerning the number of procedures performed in the state as well as other states' CON regulations regarding vascular surgery.

Recommendation: The CON Commission accepts the NEWTAC recommendation to not place interventional neuroradiology services under CON review.

CERTIFICATE OF NEED
Compliance Activity Report to the CON Commission
September 18, 2007

This compliance report will be provided to the CON Commission on a quarterly basis and is designed to update the Commission on the Department's activity in monitoring compliance with all Certificates of Need issued as required by Section 22247 of the Public Health Code. This first report details activities from March 1 through September 12, 2007.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:
(a) Revoke or suspend the certificate of need.
(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.
(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.
(d) Request enforcement action under section 22253.
(e) Take any other enforcement action authorized by this code.
(f) Publicize or report the violation or enforcement action, or both, to any person.
(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department has performed follow up checks on approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222 of the Code, as demonstrated below.

- 560 follow up letters have been mailed
- 270 projects have been reported as 100% complete and operational
- 24 projects expired due to noncompliance with Part 222

Compliance: In accordance with Section 22247 and Rule 9419, the Department has performed compliance checks on approved and operational Certificates of Need to determine if projects have been implemented in accordance with Part 222 of the Code, as demonstrated below.

Statewide volume checks have been performed on Open Heart Surgery, Transplantation, and Air Ambulance services as well as the Short-Term Nursing Care Programs (Swing Beds). These reviews determined compliance with primary volume requirement for each applicable service.

- 5 open heart surgery service programs investigated; 3 later demonstrated compliance; 2 programs entered into compliance agreements
- 2 pancreas transplantation programs investigated; both have voluntarily surrendered their CONs and will cease service by the end of October
- 1 swing bed program under an ongoing investigation as a result of an allegation made of noncompliance with transfer of patients in accordance with MCL 333.22210
- No compliance action required for Air Ambulance Services

CERTIFICATE OF NEED

Quarterly Program Section Activity Report to the CON Commission

April 1, 2007 through June 30, 2007 (FY 2007)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the Program Section in accordance with Section 22215(1)(e) of the Public Health Code.

Measures

Administrative Rule 325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	136	420
Letters of Intent Processed within 15 days	136	419

Administrative Rule 325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application.

Activity	Most Recent Quarter	Year-to-Date
Applications Received	69	224
Applications Processed within 15 Days	69	224
Applications Incomplete/More Information Needed	57	198

Administrative rules 325.9206 and 325.9207 requires the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	33	2	108	2
Substantive Applications	39	1	131	1
Comparative Review Applications	0	0	10	0

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Administrative Rule 325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	Most Recent Quarter	Year-to-Date
Emergency Applications Received	1	4
Decisions Issued within 10 workings Days	1	4

Measures – continued

Administrative Rule 325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	19	0	49	0

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	33	119
FOIA Requests Processed on Time	33	119
Number of Applications Viewed Onsite	19	107

FOIA – Freedom of Information Act.

Source: Certificate of Need Program Review Section, Division of Health Facilities and Services, Bureau of Health Systems, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(09/01/2007)

Case Name	***Date Opened***	***Case Description***	***Status***
Unity Health, LLC, Court of Claims Docket No: 05-224-MK	03/13/06	Lawsuit filed in the Court of Claims, seeking damages based on violations of civil rights in relation to the attempt by Unity Health to obtain a CON and/or a change in the review standards to allow it to obtain a CON to establish a hospital on the eastside of Detroit.	Case #05-000224-MK-C30 and 05-536754-CK are joined---Wayne County CC will have jurisdiction of the Court of Claims case.
Unity Health, LLC, Wayne County Circuit Court	05/02/06		Discovery continues.
Pontiac Osteopathic, Administrative Tribunal Docket No.: 2006-1702 CON	03/22/06	Appeal of Denial of CON Application.	On August 14, 2007, the Final Decision Adopting P.F.D. that the CON application is denied.
Holland Surgical Center, Administrative Tribunal Docket No.: 2007-321 CON	10/24/06	Appeal of Denial of CON Application	Rec'd (5/25/07) Final Decision adopting PFD that the Department had no authority for a hearing
Mobile Diagnostic Docket No: 2007-1870 CON	03/14/07	Appeal of denial of CON application # 06-0031 to expand mobile MRI Network No. 79 by adding a second MRI unit.	Motions for Summary Disposition and response briefs filed. Awaiting final proposed decision.
Regency on the Lake-Novi, LLC Administrative Tribunal Docket No.: 2007-1988 CON	04/02/07	Appeal of Denial of CON application. Comparative Review decision including Maple Drake Real Estate, Maple Manor Rehabilitation Center Status.	Motion for Summary Disposition filed 8/24/07.

CERTIFICATE OF NEED LEGAL ACTION

(09/01/2007)

Case Name	***Date Opened***	***Case Description***	***Status***
Kalamazoo Care Operating Co., Inc. Ingham Circuit Court Docket No.: 07-599-AS	05/09/07	Plaintiff is requesting the Court grant an order of superintending control or, alternatively, a writ of mandamus requiring the Department of Community Health/Certificate of Need Section to immediately issue a proposed decision regarding plaintiff's CON application.	Proposed Decision denying Metron of Kalamazoo CON issued 6/28/07.
Maple Drake Real Estate, LLC Administrative Tribunal Docket No: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Comparative Review proposed decision including Maple Manor Rehabilitation Center and Regency on the Lake.	Motion for Summary Disposition filed 8/24/07.
Maple Manor Rehabilitation Center Administrative Tribunal Docket No.: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Approval with Regency on the Lake and Maple Drake Real Estate.	Motion for Summary Disposition filed 8/24/07.
MediLodge of Milford, LLC (AG#20073000935) DLEG Office of Administrative Hearings & Rules Docket No.: 2007-3545 CON	07/17/07	Appeal of denial of CON application.	Pre-Hearing Conference scheduled for 9/13/07.
MediLodge of Montrose, Inc. (AG#20073002174) DLEG Office of Administrative Hearings & Rules Docket No.: 2007-4038 CON	08/21/07	Comparative Review - includes Heartland HCC-Briarwood, CON Application No. 07-0008 Heartland HCC-Fostrain, CON Application No.07-0009. The latter two received a proposed approval.	Comparative Review Pre-Hearing scheduled for 10/24/07.
Metron of Kalamazoo (2007-3000872-A)	07/13/07	Appeal of Certificate of Need. Appeal of Department's Proposed Decision denying Petitioner its request to acquire an existing nursing home.	Hearing scheduled for 10/03/07.

s: chd; assign control; special; CON Leg Action; report 09-01-07

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2007												2008											
	J	F	M*	A	M	J*	J	A	S*	O*	N	D*	J	F	M*	A	M	J*	J	A	S*	O*	N	D*
Air Ambulance Services	PH		D R	•	•	• —	P		▲ F															
Cardiac Catheterization Services**	▮	▮	▮	▮	▮	▮	▮		—	P PH		▲ F			D R									
Computed Tomography (CT) Scanner Services	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	P		▲ F									
Hospital Beds (Includes LTACSs Beg. 1/07)	•	•	•	•	•	• R				PH					D R									
Magnetic Resonance Imaging (MRI) Services**	P	•	▲F—		P				▲F															
Megavoltage Radiation Therapy (MRT) Services/Units										PH					D R									
Neonatal Intensive Care Services/Beds (NICU)	PH		D R	•	•	• —	P		▲ F															
Nursing Home and Hospital Long-term Care Unit Beds**	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	P		▲ F									
Open Heart Surgery Services**	▮	▮	▮	▮	▮	▮	▮		—	P PH		▲ F			D R									
Positron Emission Tomography (PET) Scanner Services										PH					D R									
Psychiatric Beds and Services**	•	•	• R	•	•	• R	•	•	• —	P		▲ F												
Surgical Services										PH					D R									
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	PH		D R	•	•	• R	•	•	• —	P		▲ F												
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▮ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PH - Public Hearing for initial comments on review standards
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For CON Commission Approval September 18, 2007

Updated September 17, 2007

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy, Regulation & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	June 4, 2004	2008
Computed Tomography (CT) Scanner Services	June 4, 2004	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2008
Magnetic Resonance Imaging (MRI) Services	March 8, 2007	2009
Megavoltage Radiation Therapy (MRT) Services/Units	January 30, 2006	2008
Neonatal Intensive Care Services/Beds (NICU)	June 4, 2004	2010
Nursing Home and Hospital Long-Term Care Unit Beds, Addendum for Special Population Groups, and Addendum for New Design Model Pilot Program	December 3, 2004	2010
Open Heart Surgery Services	June 4, 2004	2008
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2005	2008
Psychiatric Beds and Services	October 17, 2005	2009
Surgical Services	June 5, 2006	2008
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 4, 2004	2010

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Hearing will be held in January of each year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.